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Issue 3 – 8th Feb 2019

MDR & IVDR

Interpretation and Knowledge Support File

Internal Use Only – Not for distribution to clients.

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Contents

1 Introduction

This document is intended as a support document for Medical Devices Scheme Managers and Technical Specialists when answering queries they receive from manufacturers.

It is for internal use and not to be shared in full with customers.

It provides BSI responses to questions asked on interpretation of MDR & IVDR requirements, as well as MDR specifics topics. A separate document is available for IVDR specific topics.

This document will evolve with time as BSI understanding of the requirements progress, so please always check you're using the latest revision.

This document is applicable to both BSI UK and BSI NL and supports queries related to the Regulations regardless of the impact of Brexit. This document will not deal specifically with Brexit queries which will be addressed by other communication.

Please address all inquiries to related to content and to have your questions answered in future versions of this document to james.newman@bsigroup.com.

2 GENERAL QUESTIONS

2.1 MDD Certificates

2.1.1 MDD Certificates Renewal

2.1.1.1 We have proposed renewing Design Examination Certificates "early" so that they would be valid until 2024 (per Art 120 limitations). Will BSI be doing the same for Annex II, Section 3 certificates under the MDD as we need the FQA to "support" the DE certs.

Yes. Review MDD FQA/PQA certs over last five years regardless of certificate cycle and confirm all appropriate audits performed since last recertification. Justification can be acceptable if required audits haven't been performed over the cycle but were done within the last five years (e.g. recertification, UAV, TF for each subcategory, generic device group, micro etc.). The plan for the new 5-year cycle post renewal should include all necessary audits.

2.1.1.2 How will reviews/renewals for MDD certificates work in 2018/2019?

Please refer to client communication sent out 2 June 2018 that covers the deadlines and requirements for dates of submissions and financial costs of reviews.


Client CommunicationMDD 1

2.1.2 MDD Applications

2.1.2.1 What is the date that BSI will stop accepting Directive applications?

The date is not yet confirmed but there will be a deadline that BSI will set and publish and likely to be sometime at the end of 2019.

2.1.2.2 With respect to the client communication regarding deadlines for MDD submissions in 2.5.1.1

a) Do the Dec and March deadlines only apply to early renewals or all types of reviews?

b) Will CE cert renewals due in 2019 just be treated in the normal way e.g. if a CE cert is expiring in May 2019 will they just be charged the normal rate?

c) Is there going to be an official MDD cut off when we no longer accept new MDD applications?

d) There are a few clients that have made applications and had audits but their tech file may not be available until the end of 2019 – which is cutting it close.

a) All changes and renewals that are required to be completed prior to May 26th 2020 must adhere to the deadlines in the communication. Maintenance activities which could be completed post May 2020 are excluded. BSI will prioritise all work required to be completed pre May 26th 2020 and therefore other work may take longer than expected.

b) Normal way

c) No new quotes from Sept 2018, wrap up quotes being worked on by end 2018, signed applications by end of March 2019 (dependant on reviewer availability).

d) SM will have to raise the concern that this will be too late with individual clients.

2.1.2.3 What happens if we applied under the MDD but do not receive our certificate prior to May 26th 2020?

After May 26th 2020 BSI cannot issue new MDD certificates therefore the application will be reported to the MHRA as a refusal and the manufacturer will need to reapply for MDR certification. If possible BSI may utilise some of the review time spent on technical documentation towards the MDR application. Micro visits if conducted within last 3 years this

will not need to be repeated. Initial QMS for MDR will be required. See MDP7000 for more details.

BSI believes consultations for devices incorporating medical substances and or animal tissue will be transferable to the MDR application, however some additional information may be required for MDR specific requirements related to these.

2.1.3 MDD Certificate Maintenance

2.1.3.1 How will BSI conformity assess our valid MDD certificates post MDR date of application if the MDD has been repealed?

BSI conformity assessment (audits, reviews etc.) processes will continue as per current practise until the certificate expires or become void with the exception of those aspects of the MDR that come into force and replace specific MDD requirements as defined in Article 120.

As per Article 122 " As regards the devices referred to in Article 120 (3) and (4) of this Regulation, the Directives referred to in the first paragraph shall continue to apply until 27 May 2025 to the extent necessary for the application of those paragraphs."

Per CAMD Transition Sub Group FAQ, page 10

"Moreover, the "old" NB which issued the AIMDD/MDD certificate shall continue to be responsible for the appropriate surveillance of all the applicable requirements relating to the devices it has certified. This should be agreed on between the "old" NB and the MFR on a contractual basis."

2.1.3.2 If a manufacturer had an MDR application under review, would it still be possible to make changes (that do not trigger MDR) to their MDD certificate? Some MDR applications may take over a year?

It is possible to submit and have reviewed appropriate changes to MDD certificates whilst an MDR application is in process. Manufacturers must ensure that the Scheme Manager is aware of the connections and how the changes may impact the MDR submission. Manufacturers are advised where possible not to do this as it may negatively impact or otherwise complicate the MDR submission.

2.1.3.3 For Declarations of Conformity to 93/42/EEC after 26/5/2020 is it required to include a declaration against the parts of the MDR that apply to MDD certified devices after this date?

BSIs opinion is that neither 93/42/EEC, the Blue Book, Decision No 768/2008/EC, nor the MDR require the manufacturer state they meet the MDR in part on an MDD DoC. Nor is there any requirement that would prevent a manufacturer form doing so.

2.2 MDR Transition Period (See also Article 120)

2.2.1.1 When does the Medical Devices Regulation (EU) 2017/745 (MDR) apply?

The MDR shall apply from 26 May 2020, see Art. 123 para 2 MDR.

There are however exceptions to that general rule. Some provisions apply earlier (e.g. regarding notified bodies or the Medical Device Coordination Group), some later (e.g. regarding UDI labelling). For the exceptions, see Art. 123 para 3 MDR (earlier application: a-c, i; postponed application: d –h).

Ref CAMD Transition Sub Group FAQ v1

2.2.1.2 When do the Directives 90/385/EEC, and 93/42/EEC cease to apply?

In general, the Directives 90/385/EEC and 93/42/EEC are repealed with effect from 26 May 2020, see Art. 122 MDR. However, there are some exceptions, e.g.

- in order to deal with devices that are compliant with the Directives or
- to serve as a "back up" in case EUDAMED is not fully functional at DoA

Ref CAMD Transition Sub Group FAQ v1

2.2.1.3 Is it possible to place a device, which is compliant with the MDR, on the market prior to 26 May 2020?

Yes, see Art. 120 para 5 MDR.

Manufacturers are – until 26 May 2020 normally required to place devices on the market that comply with the Directives, however Art. 120 para 5 MDR offers the option to place MDR compliant devices on the market before DoA.

Ref CAMD Transition Sub Group FAQ v1

2.2.1.4 What is the transition period for the MDR?

The new European Medical Devices Regulation was published in the Official Journal of the European Union on 5th May 2017. The Regulations entered into force on May 25th 2017, marking the start of the transition period for manufacturers selling medical devices into Europe.

The MDR, replaces the Medical Devices Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC), and has a transition period of three years. Manufacturers have

the duration of the transition period to update their technical documentation and processes to meet the new requirements.

Article 120 of the Regulation states a number of transitional provisions, and should be referred to for more detail.

2.2.1.5 *What is the so called "sell off" provision (Art. 120 para 4 MDR) about?*

It is intended to limit the time during which AIMDD/MDD compliant devices, that have already been placed on the market (either before the DoA or by virtue of Art. 120 para 3 after the DoA), may be made available e.g. by a distributor.

After May 27, 2025 these devices may not be made available/put into service (= deadline). If such devices are still within the supply chain by this date - i.e. have not reached the final user as being ready for use (e.g. the hospital) - they are not "marketable" any more.

This provision is thus primarily dealing with the "making available" of AIMD/MDD compliant devices once they have been placed on the market, e.g. within the supply chain. It does not apply to the "placing on the market" of these devices by the MFR.

Please also note, that this provision is not intended to apply to second hand sales (see recital 3). This means, once a device has been made available to the final user (e.g. the hospital) as being ready for use, the further making available of this device is not subject to/covered by the MDR.

Ref CAMD Transition Sub Group FAQ v1.

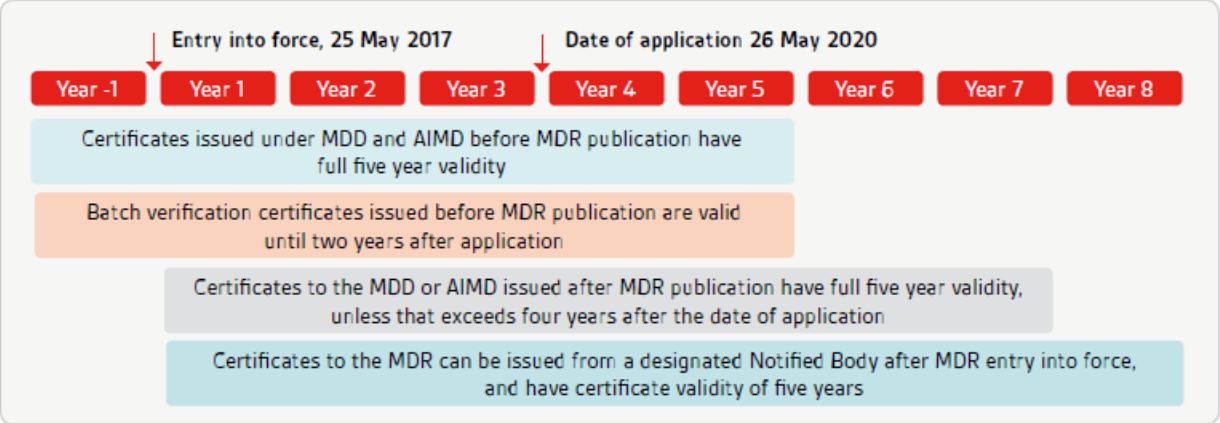
2.2.1.6 *Does Art. 120 para 4 MDR enable MFRs to place MDD/AIMDD compliant devices on the market until May 27, 2025?*

No. Art. 120 para 4 MDR is not applicable to the "placing on the market" of MDD/AIMDD compliant devices (see question 18). The only way to place MDD/AIMDD compliant devices on the market after DoA is Art. 120 para 3 MDR. Given that MDD/AIMDD certificates will no longer be valid after May 27 2024, this option ceases to exist from that date onwards.

2.2.1.7 *Will the new requirements be enforced retrospectively?*

No, the new requirements will be applied to all devices only when they are to be certified under MDR. After the transition period, devices not conforming to the MDR will need to be removed from the market.

2.2.1.8 What is the plan for implementation of the MDR?



2.2.1.9 What happens if my certificate isn't issued before the end of the transition period?

Manufacturers will have the transition period to apply for certification under the MDR for devices currently certified under the Medical Devices Directive (MDD or the Active Implantable Medical Devices Directive (AIMDD). Certificates issued to the MDD and AIMDD during the transition period will remain valid for the entire period, unless that exceeds four years after the date of application (26May2024). The validity of MDD and AIMDD certificates after the Date of Application is conditional to compliance with the provisions described in Article 120 clause 3. If do not receive certification during the transition period, and your MDD certificate expires, you will have to stop placing products on the market in the EU until they have been certified under the MDR.

Note: BSI encourages you to begin preparing for transition now, to ensure you can apply for certification as soon as possible on your Notified Body's designation to MDR. This will help to ensure certification before the end of the transition period.

2.2.1.10 What is the anticipated implementation of the MDR's by the NB's. In other words, once the NB is designated, do they review each of our CE Marked products against the MDR's only when the current certificates under the MDD are expiring? Assuming there are no additional changes submitted in the meantime.

It is the manufacture's responsibility to apply for MDR certification with the notified body once BSI has been designated.

BSI will conduct both quality system and product specific conformity assessment to the requirements of the MDR.

For quality system requirements, regardless of whether the manufacturer holds Directive or Regulation certificates, as of26/May/2020 some aspects (e.g. post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices) of the quality system will be audited to MDR requirements.

Product specific assessments will be conducted for each device (Article 52):

- Class III implants
- Class III
- Class IIb implants

Product specific assessment will be sampled for devices in Class IIb (non-implantable) and Class IIa.

2.2.1.11 *In case that after 05/2020 some medical devices are still marketed under the MDD regime and others under MDR: How can conformance to MDD and MDR be managed?*

Each manufacturer will need to determine their own strategy for this dependent on the types of devices they have and the MDR / IVDR certification they plan to apply for and the directive certification they hold / are able to maintain.

It is understood that manufacturers may choose to place devices on the market concurrently under both directives and regulations. If this is the case, appropriate CE certification will need to be in place and clear record of what devices / batches have been produced in compliance to what (regulation or directive) with corresponding records, labelling, DOC etc.

In short

- Any device catalogue number could be covered simultaneously by an MDD and an MDR certificate
- Manufacturers have to know which products were released under which DOC / certificate
- Any one device (serial number) would have to be released under one or the other DOC / certificate

2.2.1.12 *We have changes we need to make for our MDD labelling but due to large number of SKUs involved we would like to delay implementation until we redo labels for our MDR application. What transition time for MDD labelling is considered acceptable to BSI?*

The label transition time acceptance will depend on the exact circumstances. BSI will normally request a copy of your transition plan and justification for the time taken if excessive timeframe is required. BSI will expect minimal transition times for issues related to safety. For minor regulatory issues with appropriate actions in place the time frame allowable may be longer (perhaps up to 12-18months for non-critical issues that have no impact on safety). Manufactures should discuss their situation with their scheme manager and come to an agreement based on their specific circumstance.

Note – compliant information supplied will be required for MDR certification or non-conformities for quality system certificates or refusals for product related certificates may result.

2.3 How can BSI support me through the transition?

2.3.1.1 How is BSI providing information on upcoming MDR? Will BSI be providing manufactures tools to assist us?

BSI has a dedicated Medical Devices Regulation Transition webpage, bsigroup.com/MDRrevision where we post any new information, including guidance documents, webinars and other useful pieces of information designed to support you. Bookmark the MDR Transitions webpage and remain informed with the most recent updates.

You can also sign up to BSI's monthly newsletter and join our LinkedIn group to ensure you receive information and access to the newest guidance on a regular basis.

2.3.1.2 Can manufacturers have discussions with BSI on upcoming MDR related issues?

Your Scheme Manager will be open to such discussions and support you however BSI can within its remit as a Notified Body.

2.3.1.3 How will BSI transition manufacturers to MDR?

It is the manufacturer responsibility to decide when and how they apply for MDR certification with BSI.

BSI has a dedicated Medical Devices Regulation Transition webpage, bsigroup.com/MDRrevision where we post any new information, including guidance documents, webinars and other useful pieces of information designed to support you. Bookmark the MDR Transitions webpage and remain informed with the most recent updates.

You can also sign up to BSI's monthly newsletter and join our LinkedIn group to ensure you receive information and access to the newest guidance on a regular basis.

2.3.1.4 What does BSI expect to see in a Manufacturer's MDR transition plan?

The manufacturers transition plan is their responsibility. BSI suggests open communication with your Scheme Manager to ensure BSI can appropriately support your application when it is submitted.

2.3.1.5 We obtained a copy of the MDR Readiness Review document from BSI's website. Has BSI finalized a MDR audit readiness checklist? If not – when does BSI anticipate having a checklist available?

The readiness review is intended to point manufacturers in the direction of changes they need to consider in their QMS and technical documentation. BSI is currently not preparing further checklists if this situation changes updates will be communicated via the website.

https://www.bsigroup.com/en-GB/medical-devices/our-services/MDR-Revision/MDR-transition-resources/

2.3.1.6 Where can I find more information to expand my knowledge?

BSI offers a wide range of free webinars and white papers, to keep you informed on the current thinking and latest changes in the regulatory space. Take advantage of our expertise and learn more about key topics including legislation, risk and regulatory changes. BSI's suite of training courses can provide more support, from introductory courses through to more specialised programmes aimed at those with regulatory experience. Call us for more information: 0345 086 9000.

2.4 Notified Body activity

2.4.1 MDR Applications

2.4.1.1 We are currently certified under MDD with another Notified Body. Can we apply for MDR certification with BSI for the same products we have MDD certified?

Yes, MDR is a different legislation.

2.4.1.2 Can we apply for MDR certification with BSI UK if we have migrated our MDD certificate to BSI NL?

Yes, MDR is a different legislation.

2.4.1.3 What is the expected date of BSIs designation for the Medical Device Regulation (MDR)?

BSI UK has been designated under the MDR.BSI NL is estimated to be designated in H2 2019.

2.4.1.4 Will the NBs be assigned a new number upon accreditation to the MDR?

No.

2.4.1.5 Can I apply for an MDD certificate once my Notified Body is designated under the MDR?

Yes, providing you meet the conditions described in Article 120 clause 3 and your Notified Body still accepts applications under the Directives. However, these certificates will only be valid for up to four years after the date of application of the MDR, meaning some certificates will be issued with limited validity.

You also need to consider the time required for the Notified Body to perform the required conformity assessment activities and issue EC certificate against the Directive. Note that this must happen before the 26May2020.

2.4.1.6 When will BSI begin conformity assessment against the new Regulation?

All Notified Bodies can begin auditing to the new Regulation once they have been designated as a Notified Body under the new MDR by their Competent Authority.

BSI UK has been designated under the MDR. There will be an official communication to all clients from BSI on when we will start accepting MDR applications.

2.4.1.7 How long will it take to obtain MDR certification after application?

It is difficult to anticipate, but will depend on several factors such as Manufacturer readiness, quality of Manufacturer documentation, demand for MDR certification and availability of BSI resource. It is important to note that a full conformity assessment (QMS, Micro, Technical etc) will be required for certification under MDR.

2.4.1.8 When will we know in details for what activities will be required before manufacturer can be issued a cert under MDR (i.e. number of audit days (TF or DD reviews), type of audits (QMS, micro)).

Manufacturer will need to place a new application for MDR certification.

For manufactures that currently hold ISO13485/MDD certification with BSI it is likely the initial quality management system assessment duration less than a manufacturer without current ISO and MDD certification (estimated as 1-4 days depending on complexity of the manufacturers

portfolio). This assessment will be separate from any MDD surveillance audits but could be booked to immediately follow the surveillance audit.

Microbiology audits may be required depending on a manufacturers specific circumstances.

Initial technical documentation reviews will need to cover minimum of one file per category/generic device group for devices on quality system certificates and for every device on a product certificate.

2.4.1.9 *If we do not certify all our products at once, how should we plan for more than one technical file audit – does BSI have any recommendations?*

There are several recorded webinars on BSI external website on how manufacturers can prepare for MDR. It is not necessary that the application includes all the devices a manufacturer has. If the manufacturer takes a phased approach, it really depends on the Manufacturer and what their priorities are in terms of which devices they would like get certified first under MDR.

2.4.1.10 *If more than one product/product family is certified at a technical file audit, will all technical files then be review or will the audit be based on sampling? MDR defines the sampling criteria based on the classification of devices.*

We have to sample at least one representative device per Category for class IIa devices and at least one representative sample per Generic Device Group for Class IIb devices.

2.4.1.11 *Does BSI see an increase in requests for sample devices for testing?*

Not in general practise no, but will be more witness testing during surveillance audits.

2.4.1.12 *What are the BSI expectations for conducting QMS Audits when QMS Entities will have Product Certs under AIMDD/MDD and MDR?*

BSI intends to conduct a single QMS/Micro audit to cover where appropriate ISO 13485, MDD, MDR and or MDSAP. For Technical documentation review BSI will combine MDD/MDR assessment wherever possible and practical.

2.4.1.13 *Can an MDR Quality System cert be issued prior to completing the technical documentation reviews if the onsite QMS assessment has been performed?*

No. An MDR Quality System Certificate requires BSI has assessed both the quality system and the technical documentation (for class I (s/m/r) no technical documentation review is required).

Whereby the manufacturer is applying for MDR certification of products already certified under MDD a phased transition from Directive to MDR is possible.

2.4.1.14 Does the grouping of products on MDR certifications dictate how products must be grouped within CER, PSUR, SSCP, etc. reports? For example, there may be advantages or disadvantages to documenting clinical evidence at a system level while maintaining separate certificates for a system and its accessories.

There may be several considerations that should be taken into account when potentially grouping some of these documents and this will be further clarified during the transition. Some of the details of the SSCP are yet unknown but it must contain information that will be clear to the end user. Class IIb non implants and lower risk devices could potentially be grouped by generic device groups and subcategories but the related reports will need to remain clear to the end user. If manufacturers wish to have multiple certificates of the same type (e.g. Annex IX or XI) this is possible.

2.4.1.15 What process will be used for the issuance of certificates? Will there be a review of certificates prior to issuance?

BSI is planning to use a process very similar to the present one which includes providing a draft certificate to the manufacturer for review and their confirmation of approval prior to issuance.

2.4.1.16 Will OBL certificates be allowed under MDR?

No. OBLs no longer exist. All manufacturers are treated the same. If a name is on the label, then they need a CE certificate and are considered the legal manufacturer. Refer to Article 16 for additional information for Virtual Manufacturers.

2.4.2 MDR Transfers

2.4.2.1 Will transfers be allowed under MDR?

BSIs currently belief is that transfers will be allowed under MDR however the process will be different. The final process has not yet been determined but it is thought that BSI will quote for a full initial application and then if possible justify a reduction in the work actually carried out where it can be appropriately substantiated by evidence of the previous NBs assessments.

2.4.3 Service Levels, BSI Resources and Fees

2.4.3.1 Will BSI be prepared for the increased workload under MDR?

BSI has been actively expanding our capacity, staffing levels, competency breadth and support systems for some time now in order to be ready for the MDR. BSI is committed to continuing this process in order to meet the future demands of the business.

Manufactures should speak to their Scheme Managers as early as possible regarding their plans and priorities.

2.4.3.2 Will technical documentation review timelines be similar as under the MDD?

BSI is currently reviewing our service level timelines for MDR and what impact the increased requirements may have in comparison to the MDD. Given the increased requirements of the MDR over the MDD BSI anticipates review times will be longer than MDD reviews.

2.4.3.3 How long have BSI set aside to review each technical file under the MDR?

External Answer

BSI is recurrently evaluating the audit/review length requirements.

Internal Answer

Current estimates (subject to change)

Class	Time
Class IIa	2-3 days
Class IIb	3 days
Class IIb active Rule 12	3 days

Class IIb implantable	3-4 days
Class III	8-10 days

2.4.3.4 Will BSI be providing expedited review services for MDR?

BSI is currently reviewing our service level timelines for MDR and what impact the increased requirements may have in comparison to the MDD. BSI will continue to have expedited options.

2.4.3.5 Will BSI be leveeing any new fees for MDR? Will costs increase?

BSI currently anticipates the general fee structure will be similar to now, although reviews may require more time given the additional requirements of the MDR. BSI will continue to work on this as part of our MDR preparations.

2.4.4 MDR Pre-assessment

2.4.4.1 Does the EU have the equivalent of a US pre-sub to address device specific questions w.r.t. new MDR prior to the submission?

External Answer

Currently BSI does not offer pre-assessment services to MDR requirements. BSI is currently working with appropriate regulatory bodies to assess whether such options may be made available in the future.

Internal Answer Only

BSi is not offering gap assessments against the MDR and IVDR for the moment.

BSI conducted limited pilot reviews with select manufacturers only as part of our designation process in order to present evidence of our processes working to the designating authorities. There will be no new pilot reviews after early April 2018.

2.4.4.2 What options exist for a pre-certification audit to MDR?

Currently BSI does not offer pre-assessment services to MDR requirements. BSI is currently working with appropriate regulatory bodies to assess whether such options may be made available in the future

2.4.4.3 *Since there will be an Expert Panel to review clinical equivalence, will that mean that BSI will no longer offer the service for a Pre-Clinical Review? If so, will there be a transition period until such Expert Panels are put in place?*

Internal Communication: Regulatory Strategy Review – email from Gary Slack – 8 December 2017

There have been significant discussions ongoing around RSR, both official and unofficial. Please take this email as confirmation of the current state of play with this critical service MHRA and IGJ (NL) have both reviewed the service and we are awaiting written confirmation for our plan outlined below.

RSR becomes Pre-Certification Assessment (PCA)

We will move to rename RSR to Pre-Certification Assessment, from 1st January 2018. The new name will be used in the internal procedures/forms, sales and marketing content. PCA will only be available with the Directives.

Please remember, we do not do PCA on Clinical Investigations Protocols (CIP) or Performance Studies.

Due to the external focus in this area, we will temporarily remove the marketing materials from the website until we have clarity going forward; the service can still be offered to prospects during one to one discussions.

MDP4130 is currently active in the system and will be updated to match the present state of play.

MDR and IVDR and PCA

Currently no commercial Pre-certification activities will occur for the Regulations during the Pilot stage. As such, we will not be launching a 'Regulation Ready' gap analysis to the Regulation during the Pilot stage.

Pilot Reviews

BSI needs to complete a number of pilot reviews to the Regulations, these will not continue after we have had our joint assessment. These reviews are pilots for BSI to prove our capabilities for the joint assessments; they are not a commercial activity.

The QMS team are still recruiting clients for Pilots; please refer suggestions to the QMS team.

Summary

- RSR becomes PCA, with minimal promotional activity
- PCA only allowed under the Directives

- No commercial Pre-certification Assessment activity will occur for the Regulations during the Pilot stage.
- The final PCA service under the Regulations will follow in 2018.

As a business, we understand this pre-certification assessment is an important service to our clients, and BSI will continue to provide the service.

2.4.4.4 Can BSI provide consulting support if they are currently our organization's Notified Body?

As a Notified Body, BSI will be unable to provide any consultancy services.

2.4.5 Commission Expert Panel

2.4.5.1 BSI mentioned ability to consult w/ Expert Panel appointed by Commission for Class III advice. What is the mechanism to request this? Is Expert Panel access available now? (Or May 2020?)

The mechanism for consulting expert panels has not yet been published. Once the system is in place BSI is willing to accompany the manufacturer to such sessions.

2.4.5.2 Will BSI Certification Panel reviews occur before or after Commission reviews?

BSI Certification Panel reviews are always the final step of the certification process, and will always happen after all the due conformity assessments, including any consultations by the Commission that have been carried out.

2.4.6 NB Review of PMS, PSUR, PMCF

2.4.6.1 Can you speak to the difference in reporting requirements from MDD to MDR for items like PMS report, PMCF, PSUR? Will the notified bodies request review at times other than audits?

BSI intends to wherever possible minimise the amount of submissions by the manufacturer (for example by combining significant change reviews with review of PSURs). Where this is not possible BSI may request addition information from the manufacturer in order to meet MDR requirements.

2.4.7 Certificate Formats

2.4.7.1 Will multiple trade names be allowed on MDR certificates (ADBA, ATA etc)

This will depend on how economic operators register their SRN. BSI's current understanding is that Eudamed for MDR will not allow this.

2.4.7.2 How will the tables for product certificates in MDP4500 work for MDD certs where the manufacturer has a table describing ranges?

Product certificate format will be updated for MDR in order to meet the requirements for certificate content prescribed by the Regulations. The level of detail may be reduced from MDD certifications and more reliance may be placed on using Basic UDI to identify devices covered by the certificate. BSI excepts the manufacturer to clearly document product codes covered by the Basic UDI in their technical documentation.

2.4.8 Other

2.4.8.1 What is required if we currently hold an Annex VI certificate?

Manufacturer will have to prepare to apply under a new route to conformity. Current Annex VI certs will remain valid until expiry or 26th May 2024 whichever comes sooner.

2.4.8.2 As we work to prepare our submission schedule for EU MDR, we are seeing that some significant change target dates could line up with EU MDR submission target date. Our concern is if the significant change is issued to the MDD certificate while an EU MDR certificate is under review, the newly issued MDR cert would miss the MDD significant change. Is it possible to incorporate a significant change into an EU MDR submission, since EU MDR submission are being treated as initial reviews?

Yes, a manufacturer can submit an MDR application that includes a significant change from the device certified under the MDD as this is a new application.

The manufacturer should communicate this is the case to their Scheme Manager for clarity and transparency on both sides.

2.4.8.3 *In a presentation (on youtube https://www.youtube.com/watch?v=Xk8bCpLUUiU&feature=youtu.be) BSI mentions that a certificate under MDR cannot be issued before 26th May 2020. Is this the case even where a NB has been designated under MDR?*

Per Article 120 para 5, once a Notified Body is designated under the MDR, then the NB will be able to issue MDR CE certificates before 26th May 2020. However, some requirements such as EUDAMED registration may not be possible before 26th May 2020.

2.4.8.4 *Will BSI have to audit distributor and importers we use before we can obtain our MDR certificates? Will they require ISO 13485 certification? Will they be listed as a significant subcontractor on our certificates? Will they be subject to UAVs?*

The MDR does not require that distributors and importers have ISO 13485 certification.

BSI does not consider distributors and importers as significant subcontractors.

BSI has no plans to specifically audit distributors and importers as part of a manufacturers MDR CE certification.

BSI QMS auditors may review the manufacturers relationship with distributors and importers and how this is managed via the QMS to meet the requirements of the MDR during QMS assessments.

Internal note – No need for distributors and importers to be on UAV form MDF4102

2.4.8.5 *Annex II, 3.4 requires unannounced audits (UAVs) every five years. Does that mean that BSI will not conducts UAVs for high classification devices every 3 years as it is under MDD?*

BSI will continue to conduct standard UAVs every 3 (Class III and IIb implantable) or every 5 years (all others).

This is currently under review to ensure alignment across Europe and may change in the future to match MDR stated requirements.

2.5 BSI Internal Business Decisions

2.5.1.1 *Will BSI offer all services under MDR?*

Please refer to BSI internal communications for the latest information. The following is taken from communication form Jane Edwards in Sept 2018.

Please find critical information regarding BSI and the MDR. Please spend ten minutes to read through the details, they will be important to your role. Thank you.

We are proud that we will remain a full scope notified body on Nando and will continue to market our services as such. The below decisions will allow us to focus on our already successful core business.

1 Type Test & Batch Release

1.1 Directives

BSI will reduce the availability under this conformity route. We will continue to be a full scope Notified Body for all NBOG codes, however for Type Test and Batch Release routes of conformity assessment under existing Medical Devices Directives:

• In the UK we can keep the existing certificates that we have, however we will not take any new Type Test/Batch Release applications other than for the codes below.

• In the NL we will not have any NBOG codes, so these certificates cannot migrate to the NL.

1.2 Regulations

Under the MDR in the UK and NL we will only take new applications for the following codes:

Medical devices, 93/42/EEC	Medical devices, EU 2017/745
General non-active, non-implantable medical devices	General non-active, non-implantable medical devices
MD 0101 Non-active devices for anaesthesia, emergency and intensive care	MDN1201 Non-active devices for anaesthesia, emergency and intensive care
MD 0107 Contraceptive medical devices	MDN1210 Contraceptive medical devices
General active medical devices	General active medical devices
MD 1103 Devices for stimulation or inhibition	MDN0305 Devices for stimulation or inhibition

Manufacturers with devices that fall within the codes above will be the only ones we can allow to apply under MDR Annex X (MDD Annex III) and MDR Annex XI Part B (MDD Annex IV).

The Scheme Managers for the manufacturers affected by this decision have already warned their certificate holders.

2 Class Ir, Devices with no Medical Purpose and Reprocess only devices.

BSI has a large number of clients and we need to ensure that we can provide an excellent service to these manufacturers. The MDR has brought a number of product classes which were not previously covered, and we would like to clarify our position on these products.

BSI will continue to work with existing manufacturers who must now include these devices in the conformity assessment work we conduct.

BSI has taken the decision to not accept products which fall under:

2.1 Class I Reusable Surgical Instruments

'Reusable surgical instrument' means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out.

As described in MDR Annex III, Article 52.7:

the involvement of the notified body in those procedures shall be limited: (c) in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

BSI will not accept applications from new manufacturers for these products.

BSI will continue to work with existing manufacturers (note including ISO 13485 only clients) who must now include these devices in the conformity assessment work we conduct.

2.2 Devices with no medical purpose

The Devices without a medical purpose will not be able to be assessed until Common Specifications are available so they are not really an issue at the moment.

BSI will not accept applications from new manufacturers for products with no medical purpose.

BSI will continue to work with existing manufacturers who must now include these devices in the conformity assessment work we conduct.

2.3 Reprocessing only applications

MDR Annex III, article 17 states, reprocessing and further use of single-use devices should only take place where permitted by national law and while complying with the requirements laid down in this Regulation. The reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device and should assume the obligations incumbent on manufacturers under this Regulation. Nevertheless, Member States should have the possibility of deciding that the obligations relating to reprocessing and re-use of single-use devices within a health institution or by an external reprocessor acting on its behalf may differ from the obligations on a manufacturer described in this Regulation. In principle, such divergence should only be permitted where reprocessing and reuse of single-use devices within a health institution or by an external reprocessor are compliant with CS that have been adopted, or, in the absence of such CS, with relevant harmonised standards and national provisions. The reprocessing of such devices should ensure an equivalent level of safety and performance to that of the corresponding initial single-use device. BSI will not accept applications from new manufacturers for re-processing of devices whether or not they are already CE marked

BSI will continue to work with existing manufacturers who we conduct conformity assessment work for.

3 Regulatory Strategy Review/CE Pre-Certification Assessment

We will no longer be promoting RSR/PCA, the ongoing reviews will be completed, but no further review services will be promoted or sold.

There is one exception; we now have confirmation from the MHRA regarding classification reviews under the Regulations. The MHRA has confirmed:

- According to the MDR and IVDR, review of the classification of the product is part of the quotation and pre-application activities (Annex VII section 4.2) and of the application review and contract (Annex VII section 4.3).
- BSI indicated that we always confirm the classification at quotation stage. In cases where the classification is a borderline one and therefore needs a thorough assessment, BSI do these under the Pre-certification Assessment service which includes provisions that the manufacturer will apply to BSI once classification is confirmed and if they don't, BSI report this as a refusal. This approach is acceptable to MHRA on the premise that classification reviews are not advertised as a stand-alone activity outside of the pre-application activities.
- BSI can also proceed with classification review during the review of the application where a contract is already in place with the manufacturer and report a refusal or withdrawal of application if for some reason the manufacturer does not proceed with certification.

A new procedure called Classification Disputes (MDP4210) and an associated form (MDF4210) are to be created to document such classification reviews. However, these classification reviews will only happen at the time of application to the Notified body for CE marking, and not early in the development lifecycle of a device as has currently occurred in a few instances.

We need to be clear that at time of application we follow the steps:

- Sales check classification with technical team as per standard quote review process
- If the product is borderline, we can do a chargeable classification review
- We will quote for this as a preliminary step to full initial application.

The procedure will also cover the process for classification disputes per MDR Article 51.2 and IVDR Article 47.2. The use of the prefix "SR" (currently used to denote Strategy Reviews) will disappear as classification reviews will be a part of the full CE application. We will not market this service as a separate product, it is part of the CE application and submission process.

2.6 BSI Netherlands and MDR

2.6.1.1 When will BSI Netherlands be designated under MDR?

BSI estimates second half of 2019.

2.6.1.2 What is BSI Netherlands NB number? Will it be the same as BSI UK?

BSI Netherlands will be allocated a NB upon designation under MDD (estimated to be Q4 2018). It will be different from BSI UKs NB number.

2.6.1.3 Will MDD/MDR certificates be migratable form BSI UK to BSI NL?

Yes, once the NB has been appropriately designated certificates can be migrated from BSI UK to BSI NL (full transfer not required). BSI will not migrate certificates from BSI NL to BSI UK.

2.6.1.4 Will BSI charge for migrating from BSI UK to BSI NL?

No.

2.6.1.5 Can a client submit an MDR application to BSI UK, even if they have migrated their MDD CE certificates to BSI NL?

Yes.

2.7 Impact of the MDR on Quality Management Systems (QMS)

2.7.1.1 Is there a deadline for my QMS to be compliant with the MDR?

All medical devices, whether currently certified to a European Medical Directive or yet to be certified, will need to comply with the requirements of the MDR to be certified under the MDR. The MDR requires manufacturers to demonstrate an effective QMS. Therefore, to receive certification to the MDR, you must have a compliant QMS within the transition period, as set out in Article 120.

In addition, from 25May2020, per Article 120.3, ALL manufacturers will have to meet the MDR requirements for post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives, even if they only hold CE certification under the Directives.

2.7.1.2 Are you expecting that manufacturers conduct an internal audit against MDR requirements and be able to confirm full compliance with the MDR at the point they submit the application for MDR Certification?

Assuming the application needs to be made several months before the MDR certification audits actually need to take place, this brings the compliance deadline forward several months. This would result in manufacturers needing to comply with both the MDD and the MDR during the period where they have applied for but not yet completed MDR certification.

As per current practice for new applications, a manufacturer will apply to BSI when they know their plans for the readiness of their Quality Management System. As part of the application with BSI the manufacturer will identify when the QMS will be ready for Stage 1 and Stage 2

audits. The application can be made before the full QMS is ready and it is recommended that BSI have the application and contract in place 3-6 months before the readiness date of the first audit.

The MDR doesn't requires an internal audit to be performed prior to application for CE marking but that the QMS addressed the topic of internal audits. It is the manufacturer's responsibility to set up and maintain their internal audit plan.

2.7.1.3 *Per EU MDR Article 52, Conformity Assessment Procedures, manufacturers of Class IIa and IIb (non-implantable) will be subject to a conformity assessment which includes assessment of their technical documentation of at least one representative device for each category of device.*

However, it is our understanding that as part of the initial QMS certification for MDR, the Notified Bodies have requested that at least one device of each class covered by the QM-System must be MDR compliant at the time of NB audit.

Does BSI agree with this approach? If not, what sampling scheme will be utilized?

Article 120 allows the exact same devices to be covered by a Directive certificate and a Regulation certificate.

To obtain a first Regulation certificate, the manufacturer will have:

QMS assessment

Technical Documentation assessment

The QMS will need to show that it is MDR compliant.

One category or group of devices can be sampled and when compliant added to the Regulation certificate.

For Class III and Class IIb implants, required to hold Technical Documentation certificates, when this review is complete the manufacturer will also receive a Technical Documentation certificate.

2.7.1.4 *We will be updating a number of SOPs and processes for compliance MDR. Does BSI recommend that the SOPs are maintained as drafts until after the QMS Certification audit?*

The SOPs would be updated for review and formally approved after acceptance per the audit outcome.

In initial audits, auditors look for an effective system. It will be necessary for the majority of aspects to be implemented prior to initial audit.

2.7.1.5 *How will the new MDR impact contract manufacturers?*

If a contract manufacturer intends to take legal manufacturer responsibility for the devices that they provide to market, they must comply with the Regulation in its entirety. If a contract manufacturer does not take legal manufacturer responsibility, the only implication is that they may be subject to audits on behalf of the legal manufacturers they provide services to. This includes unannounced audits.

2.7.1.6 *How likely do you think it is that companies will have contracts with one another to provide access to clinical data. It seems on the surface that this is an unrealistic situation.*

BSI cannot comment on manufacturer's contracts with third parties.

2.7.1.7 *Please clarify BSI's expectation in terms of audit plan and the cadence of implementing/delegating acts. Once the initial QMS audits have been completed, how will compliance be assessed for new implementing/delegating acts that were not part of the original assessment?*

Initial audits for compliance with MDR will be conducted. BSI will continue to audit to any new requirements that come into place such as implementing / delegating acts during annual surveillance unless otherwise specifically required. It is the manufacturer's responsibility to meet their obligation of implementing any changes in the timescales required per the relevant transition. Please note that after 26 May 2020, all manufacturers under MDD are required to implement certain MDR QMS aspects as described in Article 120.

2.7.1.8 *Does operating under MDR necessitate any updates to legal contracts between BSI and the legal manufacturer in terms of scope, liability, responsibility, etc.*

A manufacturer must officially apply to BSI for certification under the MDR and this will require they agree to new contract terms. No significant changes are anticipated with respect to liability and responsibilities from what they are today. We are not planning to significantly change our terms and conditions.

2.7.1.9 Will BSI require that subcontractors have ISO13485 from NBs designated under the MDR to avoid the necessity for subcontractor verification audits?

No, valid and appropriate ISO 13485 certification from EU NBs designated to MDD or MDR will be acceptable.

2.8 Technical Requirements

2.8.1 General Requirements

2.8.2 Technical Documentation requirements

2.8.2.1 Is it ok to have a single technical file that covers MDD and MDR?

Yes, providing that if certain sections apply only to one or the other that this is made explicitly clear and of course the file needs to meet both MDD and MDR requirements.

2.8.2.2 Do we have to have a MDD file to support our MDD scope if we have a MDR certificate for the same device? Do we have to maintain the MDD file?

Manufacturers that wish to maintain their MDD certificate scopes must continue to meet the requirements of the MDD including having a technical file. The manufacturer may have separate files or one technical file that covers MDD and MDR providing that if certain sections apply only to one or the other that this is made explicitly clear and of course the file needs to meet both MDD and MDR requirements. Regardless how the file is organised the MDD file must be maintained for the life of the certificate and even after that with respect to any updates required due to PMS whilst the MDD product is still on the market.

2.8.2.3 Will BSI have technical file sampling plans for MDD and MDR or combined? We will receive MDD and separate MDR technical audits or combined?

BSI will maintain separate sampling plans for MDD and MDR. Wherever possible BSI will conduct combined audits that support MDD and MDR where the manufacturer is certifying the same device under the directive and the regulations.

2.8.2.4 Would you please elaborate on the translation expectations for technical documentation?

Article 52

12.The Member State in which the notified body is established may require that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 7 and 9 to 11 be made available in an official Union language(s) determined by that Member State. In the absence of such requirement, those documents shall be available in any official Union language acceptable to the notified body. BSI UK/NL require the technical documentation be provided in English.

2.8.2.5 *What is the summary of technical documentation, and when should it be made?*

Annex II para 1, Annex II, 4 and Article 10, 8 refer to "the summary" of technical documentation.

The meaning of this is not defined in the MDR. BSIs interpretation is that this means a summary of technical documents information for all key parts of the MDR requirements but excluding test reports, protocols, copies of literature and other such supporting documents which would just be referenced. The full technical documentation would include all data and documents.

2.8.2.6 *Much of our technical documentation is stored in an electronic document system. In what form must we be able to present (publish?) our Technical Documentation from our document system?*

The manufactures technical documentation must meet requirements such as

Per Annex II, para 1 of the MDR

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

Per Annex II, 8

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

Exactly how this is achieved is the responsibility of the manufacturer.

2.8.2.7 *Do you have any technical file format document that you suggest companies use in order to show their compliance?*

BSI does not prescribe the format of technical documentation.

BSI does have some requirements in terms of file size that can be submitted electronically and preferences to allow easier review (pdf, OCRed, single document, bookmarked)

See https://www.bsigroup.com/globalassets/meddev/localfiles/en-gb/documents/bsi-md-mdr-best-practice-documentation-submissions-en-gb.pdf

The manufacturer may wish to consider Annex II and III of the MDR as well as guidance published by IMDRF (www.imdrf.org) on STED format.

2.8.2.8 *Are the requirements of Annex II and III sufficient to meet the expectations for technical documentation or must manufactures also consider state of the art guidance such as STED and NBOG documents of the contents of technical files?*

The MDR Annex II and III requirements are mandatory for demonstrating conformity to the MDR and will generally supersede other guidance.

The MDR includes a general theme of manufacturers taking into account the state of the art, BSI would therefore expect manufactures to consider the requirements of state of the art guidance on creating technical documentation and where such guidance does not direct conflict with but supports and adds to the requirements in the MDR this should be considered by the manufacturer.

See Annex VII 4.5.1 last sentence

"The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance."

2.8.2.9 *What are the expectations for virtual manufactures' technical files under MDR where the manufacturing subcontractor holds its own CE certification under MDD/MDR?*

The expectation for virtual manufacturer's technical documentation is identical to a non-virtual manufacturer.

2.8.2.10 *Can BSI provide any guidance on devices that will be upclassified under MDR?*

BSI anticipates that many of the technical documentation reviews required during MDR will take longer than manufacturers may anticipate. Manufacturers should plan accordingly and ensure their technical documentation is reviewed against the MDR requirements and updated accordingly. Manufactures may wish to consider

• As Class IIb devices are currently assessed on a sampling basis, there may be non-conformities in your technical files, which have not previously been identified. Review the most recent standards, guidance and state-of-the-art safety and performance expectations for your devices to ensure that the technical documentation is up to date and compliant;

• Although rationales can be accepted in some instances for non-compliance with standards, “legacy” status cannot be used as a blanket reason for lack of test data or other documentation required by the Regulation. The requirements for risk management documentation, in particular, are called out within the Regulation, and should be linked closely to the clinical evaluation, PMS and PMCF plans.

• Equivalence data is not routinely accepted in the post-market phase, although exceptions may be made for some lower risk devices and accessories. Manufacturers should be collecting data on their own devices, and have appropriate PMCF mechanisms in place to ensure adequate data collection. Clinical data should address safety, performance and benefit-risk, cover the full range of device variants and treatment indications, and should be of sufficient quantity and quality to demonstrate scientific validity of conclusions;

• Similarly, sales and complaints data is not normally considered to be sufficient clinical data, as it does not address performance or risk-benefit, and is considered a weak data set for safety due to reporting bias;

• Clinical and technical data should be clearly mapped to each design variant. Grouped data covering more than one design variant could mask poorer performance of one of the variants;

• If you have several devices that will require a technical documentation certificate, consider staggering the dates of certificate issue, so that you are not faced with several simultaneous renewal applications in subsequent years.

2.8.3 Requirements for device-drug combinations

2.8.3.1 How does the MDR impact the regulation of device-drug combination products?

In theory, there are no changes to the principles of conformity assessment of device-drug combinations with the MDR, unless the device itself requires the additional scrutiny procedure. The additional requirements for UDI, PMS, clinical evaluation etc. introduced by the MDR will also apply to these devices. However, the words ‘liable to act’ have been removed from Rule 14, so there may be more devices requiring medicinal consultation.

There are also some additional requirements descried in Article 117 for manufacturers of drug delivery products.

2.8.4 Requirements for devices containing tissue of animal origin

2.8.4.1 Can you summarize any impact of the MDR on devices containing tissues of animal origin and how they are regulated?

The wording of Rule 18 has changed to include devices using cells or tissues of human origin. However, there will be no change in the way that devices utilizing tissues of animal origin are assessed, other than to include the additional requirements for UDI, PMS, clinical evaluation etc.

2.9 State of the Art Guidance

2.9.1.1 Although the current MEDDEVs provide guidance only to the MDD will those that provide general guidance beyond what is defined in the MDR such as MEDDEV 2.1/5, MEDDEV 2.2/3, MEDDEV 2.7.1 and MEDDEV 2.12/2 still be considered "state of the art"? Will BSI expect manufacturers to consider such guidance when and when no other guidance or less detailed guidance is available in the MDR?

BSI's current position is that the requirements of the MDR supersedes all other texts. Where existing publicly available guidance covers gaps in the MDR or adds additional requirements these may be considered "state of the art" and may still apply even if they only refer to the MDD. BSI expects that many key guidance such as MEDDEVs will be reissued in some form to refer to the MDR. BSI also believes decisions made in documents such as the Borderlines Manual published by the EU Commission will in general continue to apply unless strictly altered in the MDR text.

2.10 Interface with other EU Directives

2.10.1.1 How do RED directive and MDR relate (regarding wireless medical devices)?

The RED (Radio Equipment Directive), 2014/53/EU, is applicable to medical wireless devices that meet the definition of Article 2.1(1) of the RED as an "electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radio determination, or an electrical or electronic product which must be completed with an accessory, such as antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radio determination".

Devices within the scope of the MDR 2017/745/EU are not exempt from meeting the requirements of the RED.

A medical device within the scope of the MDR and RED must meet the requirements of them both.

3 RECITALS

3.1.1.1 The PPE Directive has now become the PPE Regulation. The MDD/MDR refers to the PPE Directive only. Should we be looking for the Directive or the Regulations going forward?

There are obsolete references in other EU legislation, and BSI believe we are allowed to work with the most up to date Directive/Regulation.

There is a chance that there will be a corrigendum to the MDR/IVDR at the end of 2018, where this will be clarified.

3.2 CHAPTER I - SCOPE AND DEFINITIONS

3.2.1 Article 1 - Subject matter and scope

3.2.2 Article 2 - Definitions

3.2.2.1 With reference to Article 2, 5 and 58 and Annex VIII, rule 11. What is the difference between clinical intervention and surgical intervention?

BSIs current interpretation is that

Surgical intervention is “clinical intervention” that requires surgery.

Clinical intervention is action by a medical professional action to intentionally become involved in a difficult situation in order to improve it or prevent from getting worse in the context of a medical disorder.

3.2.2.2 What effect has the change in definition of “active device” had with the MDR? Will some devices previously “non-active” become “active”?

The change of definition is more clarification than significant change. The removal of power and widening of the scope of Energy from just electrical is more scientifically correct. The inclusion in the definition of acting by a change of density makes explicit what was included in the guidance Med2.4/1 rev 9 (classification), namely that “significant change” of transmitted energy included density of energy. Because this is now explicit in the regulation, devices such as laser hand pieces that focus or significantly change the energy density of the working beam are likely to be active devices.

3.2.2.3 Does the definition of nanomaterials include lubricious coatings on devices?

Yes. Definitions for nanomaterial related terms are available in MDR Article 2.18 – 2.21 and these should be taken into account by Manufacturers to determine if any of them apply to their devices. The guidance document from SCENIHR quotes several examples of uses of nanomaterials in medical devices and one of them is "Nanosilver or other nanomaterials used as coatings on implants and catheters"

3.2.2.4 Article 2 does not define side effect. What is BSIs interpretation of what a side effect is?

BSI believes a side effect as something that happens when the device is working as intended and that is a known event that can occur as part of the treatment.

3.2.2.5 How is the role of the Importer defined?

The role of the Importer is defined in Article 2, 33 and obligations in Article 13.

3.2.2.6 Is an App Store considered a distributor?

"Distributor" is defined as any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service. 'Putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose. Based on these definitions at the moment BSI would consider an App store as a distributor since they are in the supply chain that makes the app available to the end user.

3.2.3 Article 3 - Amendment of certain definitions

3.2.4 Article 4 - Regulatory status of products

3.3 CHAPTER II - MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT

3.3.1 Article 5 - Placing on the market and putting into service

3.3.2 Article 6 - Distance sales

3.3.3 Article 7 - Claims

3.3.4 Article 8 - Use of harmonised standards

3.3.4.1 Will the harmonised standards under MDD be harmonised under MDR? Will there be separate lists for MDD/MDR published in the Official Journal?

MDR Harmonised standards list will be separate from MDD Harmonised standards list. BSI expects that MDR harmonisation will prioritise critical standards that apply to many devices first.

3.3.4.2 Is use of harmonised standards mandatory?

No, however consideration of harmonised standards is expected as they represent the state of the art as required by Annex I, 1.

Also refer to Annex VII, 4.5.1

“The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.”

3.3.4.3 When will the MDD Harmonised Standards be Harmonised under MDR?

BSI anticipates it will take some time for the standard bodies to establish a MDR Harmonised standards list and will probably be focused initially on horizontal critical standards first. BSI will be monitoring the situation closely.

3.3.4.4 What level of detail is expected regarding documenting conformity with standards?

Annex II, 4

(c) the harmonised standards, CS or other solutions applied; and (d) the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

3.3.5 Article 9 - Common specifications

3.3.5.1 What is a Common Specification?

Article 2.71 of the MDR defines Common Specification as "a set of technical and/or clinical requirements other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system."

3.3.5.2 When will Common Specifications be published?

This isn't yet clear. The only information available on Common Specifications currently is that these will apply to devices with no medical purpose and devices to be reprocessed.

Internal Information only

Euromcontact has prepared a proposal for a CS for non-corrective contact lenses and submitted this to the Commission. However, no competent authority has currently been appointed nor volunteered to be the rapporteur for this CS.

BSI has seen a draft common specification for reprocessing. The regulatory team is working with the Commission on this and will share with the wider MD team when allowed.

3.3.5.3 Who will write the Common Specifications?

The EU Commission is responsible for adopting Common Specifications in consultation with the MDCG (Medical Devices Coordination Group).

3.3.5.4 Where there is a CS and a Harmonised Standard for a device which will take precedents?

Per Article 9, 3 “manufacturers shall comply with the CS referred to in paragraph 1 unless they can duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto”.

3.3.5.5 What is the process for establishing common specifications?

Please see Article 9,1. BSI is not aware for further details at this time.

3.3.6 Article 10 - General obligations of manufacturers

3.3.6.1 If the manufacturing site and the AR, importer, etc are all under the same company, are agreements needed between sites of the same company?

Yes.

3.3.6.2 Can an EU based manufacturer have a EU rep?

Referring to the definitions

MDD Article 1

(j) ‘authorised representative’ means any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive;

MDR Article 2

(32) ‘authorised representative’ means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

The definitions suggest that this is allowable under MDD but not under MDR however BSI suggest manufacturers may wish to consider obtaining legal advice on this point.

3.3.6.3 If "Manufacturers" have "ultimate responsibility" for compliance, do you expect a manufacturer's planned audit activity to expand to the QMS of importers, distributors, and authorized reps?

The wording 'ultimate responsibility' comes from The Blue Guide (latest version published 2016).

Responsibilities of the manufacturer are covered in Article 10.

Article 10 states

The quality management system shall address at least the following aspects:

(d) resource management, including selection and control of suppliers and sub-contractors;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) management of corrective and preventive actions and verification of their effectiveness;

(m) processes for monitoring and measurement of output, data analysis and product improvement.

Distributors, importers and Authorised representative may be considered as suppliers of services to the manufacturer. In addition, the regulations cover many requirements which have involvement between each economic operator (for example PMS) that the manufacturer may wish to consider regardless of how the Regulations specify particular responsibility.

3.3.6.4 Which economic operator has to register the devices?

The responsibilities of the economics operators can be found in Article 10 -14, 16 and 17. Particular attention should be applied to the following.

Article 10

7.Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31.

Article 11

3.(c) comply with the registration obligations laid down in Article 31 and verify that the manufacturer has complied with the registration obligations laid down in Articles 27 and 29;

4.The mandate referred to in paragraph 3 of this Article shall not delegate the manufacturer's obligations laid down in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12).

Article 13

2.In order to place a device on the market, importers shall verify that:

(d) where applicable, a UDI has been assigned by the manufacturer in accordance with Article 27.

4.Importers shall verify that the device is registered in the electronic system in accordance with Article 29. Importers shall add their details to the registration in accordance with Article 31.

Article 14

2.Before making a device available on the market, distributors shall verify that all of the following requirements are met:

(d) that, where applicable, a UDI has been assigned by the manufacturer.

Article 16

1.A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following: ...

3.3.7 Article 11 - Authorised representative

3.3.7.1 In article 11 (1), it refers to the sole authorised representative - is this still per product?

Yes, refer to Article 11(1)

Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative.

3.3.7.2 Do you have a new agreement template for the AR and Manufactures?

No, this is not within the remit of the Notified Body.

3.3.7.3 How do you expect the AR to verify the DoC, Tech documentation and conformity assessment?

This process and output should be documented in the quality management of the authorised representative.

3.3.7.4 What would happen to an EU representative in UK? Because UK would not be an EU country.

BSI does not know the answer to this, however there is precedent of non-EU countries being allowed EU reps.

3.3.8 Article 12 - Change of authorised representative

3.3.9 Article 13 - General obligations of importers

3.3.9.1 The obligations of importers/distributors to verify e.g. DoC, CE certificate before making available on the market, is this obliged for every batch of a device or only for the first time a device model is made available?

Importers

Per Article 13

1.Importers shall place on the Union market only devices that are in conformity with this Regulation.

2.In order to place a device on the market, importers shall verify that:

Per Article 2

(28) 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market;

Distributors

1.When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2.Before making a device available on the market, distributors shall verify that all of the following requirements are met:

Per Article 2

(27) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

3.3.9.2 With reference to Article 13 – 3. "Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer."

Can the information regarding the importer be included on the packing list or commercial invoice to fulfil this requirement?

The requirement from Article 13 (i.e. indicate on the device or on its packaging or in a document accompanying the device) is to allow traceability of the actors and ensure that the importer is identified in case of issue with the device. The Packing List or Commercial Invoice

don't necessarily stay with the device up to the end-user so unless the manufacturer can demonstrate that this is the case every time then this would not be sufficient to meet the requirements.

3.3.10 Article 14 - General obligations of distributors

3.3.10.1 How far down the distribution chain do the distributors have the responsibility of the distributor?

The requirements of Article 14 include the full transport of the device to the end user and feedback from end users.

3.3.10.2 What does it mean that the distributor has to check for the IFU presence . Has to open the package?

Per Article 14

2.Before making a device available on the market, distributors shall verify that all of the following requirements are met:

(b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11);

In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.

Per Article 10(11)

11.Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

The MDR does not prescribe the method by which the distributor confirms this, only that it may be done on a sampling basis.

3.3.10.3 The obligations of importers/distributors to verify e.g. DoC, CE certificate before making available on the market, is this obliged for every batch of a device or only for the first time a device model is made available?

Importers

Per Article 13

1.Importers shall place on the Union market only devices that are in conformity with this Regulation.

2.In order to place a device on the market, importers shall verify that:

Per Article 2

(28) 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market;

Distributors

1.When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2.Before making a device available on the market, distributors shall verify that all of the following requirements are met:

Per Article 2

(27) 'making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

3.3.10.4 Where a manufacture utilises several entities in the distribution chain (which may or may not be actively involved in moving product to or from their facility) that each undertake different aspects of the distribution process is it allowable to spread the requirements of Article 14 amongst the different entities?

Yes, QMS auditors will check process to check requirements met overall.

3.3.11 Article 15 - Person responsible for regulatory compliance

3.3.11.1 Does the manufacturer have to document who is the PRRC?

Yes, in order to demonstrate compliance with the requirements.

3.3.11.2 Per Article 15 "Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance". The word organisation here is not clearly defined. Can an individual who is not an employee of the legal manufacturer but is employed by a corporate

entity that owns the legal manufacturer be the PRRC? Furthermore, can that individual be the PRRC for multiple legal manufacturers owned by the same corporate entity.

The PRRC role may not be subcontracted by manufacturers unless they fall under the Article 15, 2 exceptions for Micro and small enterprises. Employment of an individual by a corporate entity not the legal manufacturer and would result in the role being subcontracted.

3.3.11.3 Can the PRRC for the manufacturer and the Authorised Representative be the same person?

No. The intent of the regulations is that the authorised rep add an addition level of scrutiny over the device, this would not be possible if they were the same person. BSI is aware of forth coming MHRA guidance which may become European wide guidance in the future.

Internal Only

BSI has copy of draft MHRA guidance available for internal use only.

3.3.11.4 Does the PRRC have to have particular expertise in the manufacturers devices? Should there be different PRRCs for different product families?

Article 15 States

"who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices."

There is no requirement for specific technical expertise though the manufacturer may decide this is needed. Manufacturers should document evidence of the selected person's competence.

3.3.11.5 Is a person with 4 years of regulatory affairs relating to in vitro diagnostic medical devices able to be a person responsible for medical devices and vice versa?

Per Article 15

1.Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

The requirement in the MDR is for the person to have the "requisite expertise". The MDD/IVD and MDR/IVDR requirements have many differences. Experience in only one may not be sufficient for the manufactures requirements. The manufacturer should be able to substantiate the expertise of the individual employed in this role.

3.3.11.6 Does the PRRC have the same responsibilities when employed by the Manufacturer and by the EU Authorised Representative?

No, MHRA have drafted a position paper to indicate that the manufacturer is responsible for all aspects of Article 15 (3), and the EU AR has some responsibility for Article 15 (3) b) and d).

This guidance should be made available to the public early in 2018.

3.3.11.7 Is the release of a batch of the medical device an activity to be done by the person responsible for regulatory compliance?

Per Article 15

3.The person responsible for regulatory compliance shall at least be responsible for ensuring that: (a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

3.3.11.8 Is the person responsible for regulatory compliance equivalent to the concept of the management representative under the QMS?

No, however they could be the same person.

3.3.11.9 Can an Authorised Rep employ a PRRC from outside Europe?

Authorised representatives may not employ a person responsible for regulatory compliance who is situated outside of the EU. This is to ensure that the person responsible for regulatory compliance is able to have full access to Eudamed in order to fulfil their obligations.

3.3.12 Article 16 - Cases in which obligations of manufacturers apply to importers, distributors or other persons

3.3.12.1 Does Article 16, 4 "the distributor or importer shall submit to the competent authority a certificate" refer to a CE certificate? Does this mean distributor/importers need CE certification? How does this work? How does this work with Eudamed?

BSI believes this this will be controlled by individual CAs, we don't know how this will work yet. It has not been made clear whether this refers to CE certificates or other type of certificate such as ISO 1345.

BSI's current understanding is that these certificates will not be in EUDAMED.

3.3.13 Article 17 - Single-use devices and their reprocessing

3.3.13.1 What certification is section 5 referring to?

"5.The Commission shall adopt, in accordance with Article 9(1), the necessary CS referred to in point (b) of paragraph 3 by 26 May 2020. Those CS shall be consistent with the latest scientific evidence and shall address the application of the general requirements on safety and performance laid down in in this Regulation. In the event that those CS are not adopted by 26 May 2020, reprocessing shall be performed in accordance with any relevant harmonised standards and national provisions that cover the aspects outlined in point (b) of paragraph 3. Compliance with CS or, in the absence of CS, with any relevant harmonised standards and national provisions, shall be ***certified*** *by a notified body."*

BSI is waiting for clarification for the EU Commission on how this will be implemented.

3.3.14 Article 18 - Implant card and information to be supplied to the patient with an implanted device

3.3.14.1 Does Article 18 force manufacturers to have a website to communicate with patients of implants?

Yes, a website is a requirement per Article 18, 1, para 2.

3.3.14.2 Do implant cards have to be provided retrospectively for devices already placed on the market?

No.

3.3.14.3 Is the expectation that along with the Implant card, the manufacturer also provides a patient leaflet with EVERY single implant card?

The manufacturer must justify how they are demonstrating compliance with Article 18:

Per Art. 18 clause 1:

"The manufacturer of an implantable device shall provide together with the device the following:

……..

The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow rapid access to that information and shall be stated in the language(s) determined by the concerned Member State."

3.3.14.4 Does all the information in Article 18, 1 a-d have to be on the implant card or can it be supplied a different way?

Only the information per Article 18 (1a) must be on the physical implant card

Per Article 18 1 final paragraph

"In addition, the manufacturer shall provide the information referred to in point (a) of the first subparagraph on an implant card delivered with the device."

Point (a) states

(a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

3.3.14.5 Can the information in b-d of Article 18 be provided on a website instead of a paper copy?

The manufacturer must be able to justify how this meets clause 1, para 1

"1. The manufacturer of an implantable device shall provide <u>together with the device</u> the following:"

3.3.14.6 Is it possible to identify the manufacturer website via a QR Code or should a WWW domain be present as well?

No, it is not expected that users/patients would be able to access the information easily via a QR code. The www website domain should be identified. The patient must be able to readily understand the information and get rapid access to the information on the website.

Per Article 18 clause 1: "The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate. Updates of the information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph."

3.3.14.7 Can blank implant cards be provided to the healthcare institution and these blank cards used in conjunction with adhesive labels provided in the device packaging that contain the necessary information from Article 18,1(a)?

The manufacturer must be able to justify how this meets clause 1, para 3

"In addition, the manufacturer shall provide the information referred to in point (a) of the first subparagraph on an implant card delivered with the device."

It is not expected that pre-supplied generic blank implant cards will be an acceptable Article 18 solution

3.3.14.8 We plan to have the same implant card for US, EU and Australia. Is it acceptable to have Australia's sponsor address on the card?

Yes, this could be acceptable as long as all Article 18 requirements are met and the required Article 18 information is clear and can be readily understood by a lay person.

3.3.14.9 Is it required to have EU Authorized Representative Address on the card to represent manufacturer's address?

It is not currently a requirement to include the EU Authorized Representative address on the implant card. The manufacturer name and address must be included.

3.3.14.10 *Is it acceptable to leave space for hospitals to add additional information (e.g. Regional requirements, name of doctors performing implant, name/address of healthcare centers performing the implants, physician requests: medication, duration, and dosage)?*

The MDR does not restrict the addition of additional information. All Article 18 requirements must be met and the information must be clear and can be readily understood by a lay person. The manufacturer may wish to ensure that inclusion of such information is not restricted by other legislation outside of the MDR.

3.3.14.11 *If the lifetime is on the implant card visible to all patients, will they pick one hip with a 25 year lifetime instead of a second hip with a 30 year lifetime?*

As indicated in Article 18

"The manufacturer shall provide the information referred to in point (a) of the first subparagraph on an implant card delivered with the device." where point (a) lists "information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer"

This does not indicate that the actual lifetime needs to be printed on the implant card.

Article 18 (c) states

(c) any information about the expected lifetime of the device and any necessary follow-up;

Lifetime shall be made available to the end user per Article 18 requirements.

3.3.14.12 *Do we need to put both the DI and PI on the implant card?*

Both

Per Article 18

1.The manufacturer of an implantable device shall provide together with the device the following: (a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

Per Article 27, 1(a) the UDI comprises both UDI-DI and UDI-PI.

3.3.14.13 Does the UDI on the implant card need to be human readable, or machine readable, or both?

Per Article 18 (1a)

1.The manufacturer of an implantable device shall provide together with the device the following: (a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

Therefore, the 'UDI' is required on the implant card

Annex VI, Part C.1

Unique Device Identifier ('UDI') The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

Furthermore, Article 1, requires "The information shall be written in a way that is readily understood by a lay person"

Use of a UDI carrier as a means of conveying the UDI using AIDC only and not using HRI does not meet the requirements of being easily understood by a lay person.

AIDC and HRI are defined in Annex VI Pact C.1

Therefore, human readable is required as the 'UDI' is defined as human readable characters and the information shall be written in a way that is readily understood by a lay person"

3.3.14.14 Are there any GDPR privacy concerns regarding the "identity" of the patient?

It is the manufacturers responsibility to ensure GDPR compliance.

Per Article 18 clause 2, only the physical implant card provided to the patient by the health institution shall bear the identity of the patient.

3.3.14.15 *I understand that Implant Cards are not required for stand-alone sutures. What about an implantable device that includes attached sutures? Do all the requirements of Article 18 apply to both the implant and the suture in this case?*

Yes, the requirements would apply to the whole device including all components.

3.3.14.16 *Which sub-sections of Annex I part 23 apply to the implant card?*

Article 18 specifically refers to SPR 23.4 point (u):

"(u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed"

Per SPR 23.4: The instructions for use shall contain all of the following particulars:

(aa) information to be supplied to the patient with an implanted device in accordance with Article 18

3.3.14.17 *Do the exceptions in Article 18 include preloaded suture delivery devices?*

Yes, as the only implantable part is the suture itself.

3.3.14.18 *Does the requirement for implant cards and other information supplied per Article 18 apply to resorbable implants?*

Yes, all implants not on the exception list must have an implant card

Article 18 indicates the devices that are exempt from the requirement for an Implant Card.

3.3.14.19 *Should the implant card describe the rate of absorption for absorbable implants?*

Article 18 requires the manufacturer provide with the device

(c) any information about the expected lifetime of the device and any necessary follow-up;

(d) any other information to ensure safe use of the device by the patient, including the information in point (u) of Section 23.4 of Annex I.

The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow rapid access to that information and shall be stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate. Updates of the

information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph.

In addition, the manufacturer shall provide the information referred to in point (a) of the first subparagraph on an implant card delivered with the device.

Article 18 does not specifically call out "rate of absorption". The manufacturer must determine what information is required under point 1c and 1d of Article 18.

3.3.15 Article 19 - EU declaration of conformity

3.3.15.1 I saw that in the DoC the UDI shall be inserted. Does it imply that the DoC will be referred to the device lot and not only to the device type (the previous MDD did not specify this aspect)?

Per Annex IV, 3 the DoC shall contain the Basic UDI-DI as referred to in Part C of Annex VI;

Per Annex VI, C

The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

Lot number is part of the UDI PI which is not required on the DoC.

3.3.15.2 Does a manufacturer need a DoC for each regulation or directive that applies to a device?

Please refer to Article 19, there should be one DoC that covers everything.

"2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device. The declaration shall contain all the information required for identification of the Union legislation to which the declaration relates. 3.By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device."

3.3.15.3 Can the manufacturer have multiple devices on one DoC?

Yes (though it should be clear what information on the DoC applies to which products if it is not consistent).

3.3.16 Article 20 - CE marking of conformity

3.3.16.1 *Per Article 20 "The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging."*

Do Class I(r) devices have to be directly marked with CE 0086 or can the CE 0086 only appear on the packaging?

There is not specific requirement to have 0086 on device, it can be on the packaging, presuming the device is supplied with packaging.

However, per Annex VI 4.10. Devices that are reusable shall bear a UDI carrier on the device itself. See Art 123g for deadlines.

3.3.16.2 *Can Class I(r) devices be marked with CE 0086 prior to issuance of MDR certificate for these devices?*

No. The CE mark can only be applied once the manufacturer has completed the appropriate conformity assessment process.

3.3.16.3 *Does CExxxx only need to be on promotional material (including websites) 'which mentions that a device fulfils the requirements of CE marking?'*

Yes. If the material does not include such statement it does not require the CE mark. Note that the NB may still ask to review promotional material during conformity assessment to ensure the material and technical documentation are in alignment.

3.3.16.4 *Per Article 20, 5 "The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking." How will the NB check this? Do manufacturers need to include promotional material in the technical documentation? The MDR does not appear to require this?*

The MDR does not require that promotional material is included in the technical documentation.

GHTF STED Guidance SG1/N011R17 section 7.4 include guidance to summarize or reference or contain instructions for use; other literature or training materials;

MEDDEV 2.7.1 defines "Information materials supplied by the manufacturer": for the purpose of this document, this refers to the labelling, instructions for use and the manufacturer's promotional materials for the device under evaluation. Furthermore, section 6.3,7 and Appendix A3 all refer to requirements related to promotional material review as part of the CER.

As it is expected that manufacturers continue to utilise state of the art guidance on medical devices regardless of whether it specifically refers to the MDR BSI would expect manufacturers to provided references and review of promotional materials where appropriate within the technical documentation, though the promotional materials themselves could be stored elsewhere in the QMS and provided upon request

3.3.16.5 Per Article 20, 6 "Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation." Does this apply if the same labelling is used for MDD/MDR?

BSIs current interpretation is that the manufacturer needs to include a statement in the label making it clear which legislation the device meets. This could include MDD and MDR if the device is certified under both legislations.

3.3.17 Article 21 - Devices for special purposes

3.3.18 Article 22 - Systems and procedure packs

3.3.18.1 Can procedure packs be made up of CE marked devices that are CE marked under MDD and devices CE marked under MDR?

The Commission's current interpretation is that this is not allowable. This situation is currently under discussion with Commission, CAMD and NBs and may change.

3.3.19 Article 23 - Parts and components

3.3.20 Article 24 Free movement

3.4 CHAPTER III - IDENTIFICATION AND TRACEABILITY OF DEVICES, REGISTRATION OF DEVICES AND OF ECONOMIC OPERATORS, SUMMARY OF SAFETY AND CLINICAL PERFORMANCE, EUROPEAN DATABASE ON MEDICAL DEVICES

3.4.1 Article 25 - Identification within the supply chain

3.4.2 Article 26 - Medical devices nomenclature

3.4.2.1 What is the current state of making the nomenclature system available free to manufacturers? Will this be GMDN?

BSI expect this will be GMDN but discussions are still ongoing to confirm this.

3.4.3 Article 27 - Unique Device Identification system

3.4.3.1 Can you please provide the regulation number for the UDI?

The MDR does not contain reference to specific UDI regulations, only requirements for EU UDI systems under MDR.

3.4.3.2 Is there a specific format or convention for developing the UDI? Can the legal Manufacturer create own number?

Refer to Article 27

2.The Commission shall, by means of implementing acts, designate one or several entities to operate a system for assignment of UDIs pursuant to this Regulation ('issuing entity'). That entity or those entities shall satisfy all of the following criteria:

3.4.3.3 When will I need to have implemented the use of UDIs by? Will there be a transition period for existing products?

Article 123 gives the following transition period:

"for implantable devices and for class III devices Article 27(4) shall apply from 26 May 2021. For class IIa and class IIb devices Article 27(4) shall apply from 26 May 2023. For class I devices Article 27(4) shall apply from 26 May 2025;"

Currently, BSI is unsure if these requirements will follow the transition requirements of Article 120 and Article 123, or if there will be Implementing or Delegated Acts published specific to UDI.

Note some EU countries are requiring UDI is used sooner than this. Manufacture's should, reach out to the countries authorities to confirm specific country requirements.

3.4.3.4 How will the manufacturer/NB upload information to Eudamed without having a Basic UDI? How will Eudamed provide traceability without this?

The Commission has not yet completed the specification for Eudamed therefore BSI does not yet have a specification and full understanding on how Eudamed will function. BSI will be monitoring this situation.

3.4.3.5 Will there be a database where UDIs are logged?

Yes, the European database will be EUDAMED.

3.4.3.6 At what level is the use of UDI no longer applicable, with regards to individually packaged items and items packaged in a single container?

In the case of individually packaged items, where each unit of use is individually packaged, a UDI is required on the packaging on each item. In the case of items packaged together in one container where the unit of use is not individually packaged (e.g. a box of surgical gloves), only the outer packaging requires the UDI, not each individual item. For more information, please refer to the wording of Article 27 and Annex VI.

3.4.3.7 Is the use of UDIs applicable to transport packaging and outer packaging?

The MDR requires UDI carrier on all higher levels of packaging except for the shipping containers.

3.4.3.8 Has the EU clarified the use of UDI as it relates to software-only devices?

Yes, the requirements are outlined in Annex VI Part C Section 6.5 of the Regulation.

3.4.3.9 Are the new UDI requirements aligned with the current US FDA UDI requirements?

There are some differences between the UDI requirements of the US FDA and the MDR. However, there are many similarities. Please refer to Annex VI of the Regulation for the requirements related to UDI.

3.4.3.10 Can I use a UDI issued by GS1 to meet the requirements of the MDR?

GS1 is an UDI issuing agency. If GS1 meets the requirements of UDI generating organizations as set out in Article 27 of the MDR, then the UDIs issued by GS1 will qualify under the MDR.

3.4.3.11 Will compliance with the Global Trade Item Number (GTIN) meet the UDI requirement?

The MDR does not use the word GTIN; however, it has similar requirements to those of the US FDA. It will be necessary for manufacturers to complete a gap analysis of the requirements of the EU over those of other Regulatory Authorities already requiring UDI. For more information, see Annex VI of the MDR.

3.4.3.12 If a change to the UDI Device Identifier (UDI-DI) requires an update to the EC certificate, how long will this take?

The duration for the Notified Body review will be dependent on the nature of the change.

3.4.3.13 Do you know if the hardware/software being developed for the UDI system is being developed in mind with the FMD for medicines?

BSI has no information on this.

3.4.3.14 Good afternoon, what is the difference between the basic UDI and the UDI?

Please refer to Annex VI.

Basic UDI-DI The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.

Unit of Use DI The Unit of Use DI serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.

Unique Device Identifier ('UDI') The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI.

UDI-DI The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database.

UDI-PI The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.

3.4.3.15 UDI also to be on DE certificates or only on DoC's?

Yes, UDI will be used on product certificates – See Annex XII.

3.4.3.16 In my research about UDI I found out that there also needs to be a Human Readable Identifier, is this not mandatory?

Yes, please refer to GSPR23.1 (c) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes.

3.4.3.17 Will US FDA UDI labelling be compliant with the EU MDR UDI requirement?

The USA and EU requirements are not identical only similar. The manufacturer is responsible for confirming the EU requirements are met which may require addition work beyond what is required for the USA.

3.4.4 Article 28 - UDI database

3.4.4.1 Who will set up and manage the UDI database?

Per Article 28 "The Commission, after consulting the MDCG shall set up and manage a UDI database to validate, collate, process and make available to the public the information mentioned in Part B of Annex VI."

3.4.4.2 Who enters that information into the UDI database?

Please refer to Articles 10, 11, 13, 28 and 29. The manufacturer, the authorised representative, procedure pack manufacturers and importers all have various requirements with respect to entering data.

3.4.5 Article 29 - Registration of devices

3.4.6 Article 30 - Electronic system for registration of economic operators

3.4.6.1 When will manufacturers get their SRN?

BSI is aware the Commission is working on the database and we are monitoring the situation.

3.4.6.2 Will manufacturers have to update their DoC, SSCP, Certificates and other documents that require SRN as soon as they receive their SRN or can this be done at the next update?

BSIs opinion is that

- The DoC is the legal document that allows a device to be placed on the EU market it therefore should be updated when changes occur.

- BSI certificate updated with administrative required updates may be able to wait for next revision if known projects are ongoing where it could easily be combined. In other cases it may require a specific administrative update.
- For other technical documentation BSI would expect updates as per the manufacturers QMS procedures.
- BSI is not aware of the final requirements for Eudamed, this may include specific requirements of its own with regards to SRN.

3.4.6.3 Do all devices have to be registered according to Art. 29 para 4 MDR by the DoA?

No. Even if EUDAMED is fully functional at the DoA there will be an 18-month "interim phase" (= EUDAMED fully functional but Art. 29 para 4 MDR not yet applicable) during which the different devices to be placed on the market may be registered "step by step" in EUDAMED according to Art. 29 para 4 MDR instead of nationally according to the Directives (see Art. 123 para 3 e and Art. 120 para 8 MDR). However, at the end of this "interim phase" it must be ensured that all devices of a MFR's portfolio have been registered in EUDAMED.

If EUDAMED is not fully functional until a date after the DoA, the 18-month "interim phase" will be postponed accordingly (beginning at the later of the dates referred to in point d) of Art. 123 para 3 MDR).

Ref CAMD Transition Sub Group FAQ v1.

3.4.7 Article 31 - Registration of manufacturers, authorised representatives and importers

3.4.8 Article 32 - Summary of safety and clinical performance

3.4.8.1 Does the SSCP have to be supplied for the initial technical documentation review?

Yes.

3.4.8.2 Does the SSCP have to be ready in time for the MDR QMS initial assessment?

The procedure for generating the SSCP must be ready for QMS audit and a copy of the initial SSCP must be in place for the initial technical audit.

3.4.8.3 Do we have to translate the SSCP into all languages so that it can be read by patients in all Member states?

Article 32 – "The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed."

The SSCP should therefore be available to patients in their country official language. Depending on where the device is commercialised, this could mean all Member States official languages.

3.4.8.4 Can you comment on what information and depth of information should be supplied in a SSCP? Will a template be provided?

BSI believe the EU Commission will be developing a template for manufactures to use. BSI is participating in the CIE workgroup to develop this. A draft should be available in 2018.

3.4.8.5 Given that a NB does not have to review the SSCP, how does one assess the quality of the document prior to application for CE mark?

This is not a correct statement. Per Article 32 "The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary is available."

3.4.8.6 Is an SSCP required for WET?

Yes.

3.4.9 Article 33 - European database on medical devices

3.4.9.1 Will the Commission and Member States levy fees for registration into EUDAMED?

This is allowed by the MDr (Article 31.8 and 111). BSI is monitoring the situation.

3.4.9.2 When will Eudamed be accepting reports and will all countries be available at once with a single report?

BSI estimates that this will happen in 2020. BSI will proceed ahead with MDR conformity assessment even if Eudamed is not fully operational.

3.4.9.3 How will in-country registration requirements change with launch of EUDAMED and full MDR compliance?

The manufacturer should speak directly to the relevant competent authorities.

3.4.10 Article 34 Functionality of Eudamed

3.5 CHAPTER IV - NOTIFIED BODIES

3.6 CHAPTER V - CLASSIFICATION AND CONFORMITY ASSESSMENT

3.6.1 Article 51 - Classification of devices

3.6.1.1 When should up-classified devices have a certification according to the new classification?

The manufacturer may still place such devices on the market under MDD certification under the classification per the MDD within the transition limitations described in the MDR. When the manufactures apply for certification under the MDR the classification will require updating to the MDR requirements and appropriate conformity assessment must be carried out.

Devices not currently needing a NB certificate and being upclassified will need an MDR certificate before 26May2020 to continue being placed on the market from that date.

3.6.1.2 Is a new classification being created for Class I reusable devices, that will require notified body involvement in the assessment?

Yes, Class I(r) and yes they require NB review limited to those aspects related to reusability.

3.6.2 Article 52 - Conformity assessment procedures

3.6.2.1 Has the route to conformity for Class IIb implantable devices changed?

Class IIb implantable devices will require product specific certificates - see Annex IX or Annex X of the MDR for more information. These certificates will have UDI for devices covered.

The initial assessment of the technical documentation as specified in Section 4 of Annex IX will apply for every IIb implantable device, (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors).

Changes to these certificates will require review by the Notified Body prior to them issuing a certificate that covers the devices to be placed on the market in the EU.

3.6.2.2 Which conformity assessment is meant for class I MD? In the old MDD it clearly states that Annex VII is meant for class I MD?

See Article 52 Clause 7:

Class I (non-sterile, non-measuring and non-reusable)

- Annex II, Annex III, Annex IV and Annex V

Class I (sterile, measuring and reusable)

- Annex II, Annex III, Annex IX or Annex XI (Part A), Annex IV and Annex V

3.6.2.3 Article 52 states that assessment of technical documentation will be on at least one representative device per generic device group for IIb devices and at least one representative device for each category of devices for IIa devices. How are generic device group and category defined?

Article 2(7) defines 'generic device group' as "a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;"

"Category" is not defined by the MDR.

EN ISO 15225 (non-harmonised) has a similar definition for generic device group but does not define "category" either.

Unless the EU Commission clarify the situation via publishing a corrigendum or an implementing act outlining their expectations on sampling of technical documentation for both IIa and IIb devices BSI expects the approach to be similar to currently practised under the MDD.

BSI is aware NBOG are developing guidance for all NB to follow.

3.6.2.4 For devices transferred from pharmaceutical to devices that never had a consultation previously under MDD will a new medicinal consultation be required?

Yes.

3.6.3 Article 53 - Involvement of notified bodies in conformity assessment procedures

3.6.4 Article 54 - Clinical evaluation consultation procedure for certain class III and class IIb

3.6.4.1 Per Art 54

2.The procedure referred to in paragraph 1 shall not be required for the devices referred to therein:

(b) where the device has been designed by modifying a device already marketed by the same manufacturer for the same intended purpose, provided that the manufacturer has demonstrated to the satisfaction of the notified body that the modifications do not adversely affect the benefit-risk ratio of the device; or

Is it acceptable for a device to be previously marketed under the MDD or must it be previously marketed under MDR?

The device that is being modified must have been certified under MDR.

3.6.5 Article 55 - Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices

3.6.5.1 Has the process for Art 55 been confirmed yet?

The EU Commission has not yet provided any guidance for this.

BSIs intent is to accept application for devices that fall under Art 55 and submit a pack of information appropriate for the specific device to the Commission and then amend as required based on EU Commission feedback.

3.6.6 Article 56 - Certificates of conformity

3.6.7 Article 57 - Electronic system on notified bodies and on certificates of conformity

3.6.8 Article 58 - Voluntary change of notified body

3.6.9 Article 59 - Derogation from the conformity assessment

3.6.10 Article 60 Certificate of free sale

3.7 CHAPTER VI - CLINICAL EVALUATION AND CLINICAL INVESTIGATIONS

3.7.1.1 Will MEDDEV 2.7-1 rev 4 fulfil the MDR requirements for clinical?

In most respects, yes. The equivalence criteria for Class III and IIb implants are tighter under the Regulation, and the requirements for PMS, PMCF, clinical evaluation plans and clinical evaluation update schedules are more stringently defined.

3.7.2 Article 61 - Clinical evaluation

3.7.2.1 What do you do when there is no equivalent device for clinical evaluation?

If it is Class III or an implant, the manufacturer will require a clinical investigation. For other devices, it will depend on the risk and novelty. In these cases, it is likely that appropriate clinical evidence will be required (taking into account the definition of “sufficient quantity and quality” to demonstrate safety, performance and benefit-risk of the device) Proactive PMS for legacy.

3.7.2.2 Can equivalence to a device only be claimed if the device is MDR certified?

No. However the manufacturer does need to demonstrate that the device meets the relevant MDR safety and performance requirements.

3.7.2.3 With reference to Article 61, 4, first and third indents. Does this mean that the device referred to in indent one has to meet MDR requirements for clinical evaluation or that the device has to be MDR certified?

The devices clinical documentation must meet the requirements of the MDR. If the device is MDD certified only BSI will have to conduct a review of the devices clinical documentation to confirm it meets the MDR. If this is not available, then data related ot this device will not be able to be used to support equivalence.

3.7.2.4 *With reference to Article 61, 5 second indent, does this mean for class III and implantable devices, that the device to which equivalence is claimed needs to have a clinical evaluation done per MDR requirements?*

Yes.

3.7.2.5 *Hip Replacement – would we be expected to run a study for 10 years for product already certified under the MDD?*

Per Article 61 it depends on the currently available clinical data.

6.The requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and class III devices: (a) which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation: — is based on sufficient clinical data, and — is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device, where such a CS is available;

3.7.2.6 *What is "sufficient clinical data"? How does "sufficient clinical data" change with novelty, classification, risk? What are the expectations for "legacy" devices?*

These questions are currently the subject of a Commission Working Group. BSI don't have the answers yet, but it is expected that most Class III and implantable legacy devices (with the exception of some or all of the sutures, staples, pins, connectors, etc devices listed in Article 61(6b)) will require their own data, and will not be able to continue to rely on equivalence (this is actually our understanding under the Directives, but the Regulation makes this more explicit).

3.7.2.7 *Could we accept a rationale for no clinical data (Article 61, 10) on instruments? Guide wires & catheters?*

In some cases, there could be a justification made by the manufacturer. These are the topics that are still under discussion with the Commission.

3.7.2.8 *Are trauma plates an exempt group?*

Yes, BSI consider trauma plates to be covered under the exemption wording *'sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, **plates**, wires, pins, clips or connectors'* for implant cards (Article 18); assessment of technical documentation (Article 52 / Section 4 of Annex IX) and clinical investigation (Article 61).

3.7.2.9 For equivalence, does same site in the body count for the four different tendons of the rotator cuff muscles of the shoulder?

There could be a justification made by the manufacturer.

3.7.2.10 For equivalence, does same site in the body count for hernia meshes in different parts of the abdomen?

The manufacturer needs to supply appropriate clinical data supporting each location in the abdomen that the hernia mesh is indicated for.

3.7.2.11 For demonstration of Clinical equivalence, can multiple devices be utilized to demonstrate technical and/or biological equivalence?

The manufacturer may claim more than one device is equivalent, however each device must be fully equivalent to the subject device. It is not acceptable to claim equivalence to different devices for different aspects of the subject device in order to make a whole assessment from several individually assessed aspects.

3.7.2.12 Can you claim equivalence for a second generation device to the first generation device if you are broadening an indication?

Only if the second generation device is equivalent per requirements Annex XIV, 3, particularly in terms of clinical, which for a broader indication may be difficult to justify.

3.7.2.13 Can you claim equivalence with a device from a different manufacturer?

Yes, however see requirements in Article 61, 5 regarding contracts.

3.7.2.14 Does a manufacturer need to make a contract with other manufacturer to do it's the clinical evaluation report based on equivalence always? Or this is variable with the risk class of the device?

The requirement for a contract is described in Article 61 Clause 5. This applies to implants and Class III devices. In all cases a robust challenge to access to competitor's information will be applied when considering rationales for equivalence.

Note that BSI do not consider the wording to be clear and are seeking confirmation on the interpretation.

3.7.2.15 Does Article 61, 6 indicate 'Sufficient + Common Specification' or 'Sufficient + Common Specification if there is one available'?

BSI's interpretation is 'Sufficient + Common Specification if there is one available'.

3.7.2.16 Can manufacturers rely on legacy products being on the market for a long time and complaint data only in relation to PMS?

This may be possible for simple low classification devices.

3.7.2.17 Is it possible that an implantable device could lose the CE mark under the MDR if the CER has to have the clinical data on equivalent devices removed (no longer contains sufficient clinical data) Therefore, necessitating a clinical investigation to gain CE mark under MDR (which is likely not possible due to ethics requirements)?

Yes. If manufacturers are still relying on equivalence data for Class III or implantable devices PMCF studies may be required. PMCF studies do not typically require ethics approval as long as there are no additional interventions. MedDev 2.12.2 has indicated, since the January 2012 revision, that manufacturers should undertake PMCF studies to gather data on their own devices where the original approval was based on equivalence.

3.7.2.18 In the situation where Company A has a device that is new to them but not new or novel to industry and they do not have their own device to claim equivalence to, and Company A cannot use a competitor product to claim equivalence, is human clinical data then their only option or would other clinical data be acceptable?

If a manufacturer cannot gain appropriate access to data on a device they consider equivalent then they may have to consider carrying out their own clinical trial.

3.7.2.19 in the case of licensed technology, is there now a formal expectation that communication about risks and lifecycle performance is a two-way obligation?

The MDR does not have any specific requirements with regards to licensed technology. BSI would expect a manufacturer to consider all possible sources of information for a variety of technical areas such as risk management, biocompatibility, safety, performance, clinical so this may be something the manufacture should consider when assembling the technical documentation.

3.7.3 Article 62 - General requirements regarding clinical investigations conducted to demonstrate conformity of devices

3.7.3.1 Is the Clinical Investigation/clinical study requirement for Class 3 devices a new mandatory requirement under the MDR, but not necessarily required under the Medical Device Directive, if you have a sound Clinical Evaluation Report?

The requirements of the MDR apply to MDR conformity assessment.

The requirements of the MDD apply to MDD conformity assessment.

3.7.3.2 Regarding clinical investigations: how would we proceed with obtaining review and input for a clinical study design for a Class III device?

BSI would suggest the manufacturer contact the relevant Competent Authority. BSI is not allowed to comment on clinical study design prior to certification application.

3.7.3.3 If you are acquiring s device from a different manufacturer, are you able to claim equivalence when bringing the product under your design authority? or are you still required to conduct clinical studies?

The manufacturer must determine whether there is sufficient clinical evidence to meet the requirements or whether further clinical studies are required.

3.7.3.4 Is there a process to request additional devices be placed on the exempt list?

The EU Commission has not yet published such a process.

3.7.4 Article 63 - Informed consent

3.7.5 Article 64 - Clinical investigations on incapacitated subjects

3.7.6 Article 65 - Clinical investigations on minors

3.7.7 Article 66 - Clinical investigations on pregnant or breastfeeding

3.7.8 Article 67 - Additional national measures

3.7.9 Article 68 - Clinical investigations in emergency situations

3.7.10 Article 69 - Damage compensation

3.7.10.1 *Can BSI provide more clarity on the word "any" in the context of a subject in a clinical investigation Article 69 Damage compensation 1.Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical investigation conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk. The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State in which the clinical investigation is conducted.*

Clinical Investigations are under the remit of the competent authorities and required ethics committee. Therefore, BSI cannot comment on this aspect.

3.7.11 Article 70 - Application for clinical investigations

3.7.12 Article 71 - Assessment by Member States

3.7.13 Article 72 - Conduct of a clinical investigation

3.7.14 Article 73 - Electronic system on clinical investigations

3.7.15 Article 74 - Clinical investigations regarding devices bearing the CE marking

3.7.16 Article 75 - Substantial modifications to clinical

3.7.17 Article 76 - Corrective measures to be taken by Member States and information exchange between Member States

3.7.18 Article 77 - Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination

3.7.19 Article 78 - Coordinated assessment procedure for clinical investigations

3.7.20 Article 79 - Review of coordinated assessment procedure

3.7.21 Article 80 - Recording and reporting of adverse events that occur during clinical investigations

3.7.22 Article 81 - Implementing acts

3.7.23 Article 82 Requirements regarding other clinical investigations

3.8 CHAPTER VII - POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

3.8.1 SECTION 1 - Post-market surveillance

3.8.1.1 Is it expected that clinical studies be on going through the life of the product? Since it appears that a clinical evaluation and literature review will not be substantial enough to satisfy the requirements

This is not required for all devices but may be required for some. The manufacturer should determine the studies required.

3.8.2 Article 83 - Post-market surveillance system of the manufacturer

3.8.2.1 What is BSI interpretation of MDR Article 83? Art 83 requires manufacturers to report corrective and preventive actions to the competent authorities and NB? There are definitions of corrective action in the MDR and Med Dev 2.12-1. Taken together these appear to state that manufacturers are required to report any modification we make to the device design or labelling to correct or prevent any 'undesirable situation'. This could be quite broad.

It is not clear on how this requirement will be interpreted. BSI has a number of question with the Competent Authority and awaiting a response.

MEDDEV 2.12-1 relates to vigilance reporting which is covered under Article 87 of the MDR related to 'serious incidents and field safety corrective actions'. The status of MEDDEV documents with regard to MDR is unclear, however it is unlikely that they will not be applicable to MDR unless specifically updated.

PSUR (Article 86) include the description of any preventive and corrective actions taken. PSUR for class III and implantable devices have to be submitted to and reviewed by NB annually.

Notification of significant changes to QMS and Product is a requirement under Annex IX, X, XI (same as current under the Directives)

3.8.3 Article 84 - Post-market surveillance plan

3.8.4 Article 85 - Post-market surveillance report

3.8.5 Article 86 - Periodic safety update report

3.8.5.1 Does the PSUR have to be submitted after a certificate is cancelled, as there will still be PMS (TuV told people PSUR had to be submitted even after certificates were cancelled if it was still in the lifetime of the device)?

The PSUR will not have any information for a new device.

The first required PSUR will be as defined in Article 86.

After a certificate is cancelled the Notified Body no longer has a contract with the manufacturer.

BSI are participating in the Commission Vigilance workgroup and will provide information as soon as it is available.

3.8.5.2 Once a product is MDR compliant do we have a year to write the first PSUR or is it expected that this will be done when we sign off the first MDR compliant file?

Yes. Manufactures are responsible to have a system to ensure that PSURs are submitted within the required timeframe.

Internal

See MDP4104 for further guidance on how BSI are involved.

3.8.5.3 Do PSUR requirements apply to MDD certified devices from 26 May 2020?

BSI's current understanding is that PSUR requirements do apply to MDD certified devices, however they will not be uploaded to EUDAMED PSUR requirements will be reviewed by the NB as part of normal audits.

3.8.5.4 Does the manufacturer have to keep updating a PSUR even after the CE certificate has been cancelled? If so how do manufacturers submit class III, or implantable PSURs to Eudamed?

If a certificate is cancelled BSI has no legal remit to review the PSUR. However, the manufacturer may wish to ensure they maintain their post market activities for device no longer certified but still on the EU market in case other regulatory agencies carry out any investigations based on market occurrences. It is not yet clear how this will work with EUDAMED.

3.8.6 SECTION 2 – Vigilance

3.8.7 Article 87 - Reporting of serious incidents and field safety corrective actions

3.8.8 Article 88 - Trend reporting

3.8.9 Article 89 - Analysis of serious incidents and field safety corrective actions

3.8.10 Article 90 - Analysis of vigilance data

3.8.11 Article 91 - Implementing acts

3.8.11.1 Any expected time lines for Delegating and Implementing acts circulating?

BSI has no information on this at this time and is monitoring the situation

3.8.12 Article 92 - Electronic system on vigilance and on post-market surveillance

3.8.13 SECTION 3 - Market surveillance

3.8.14 Article 93 - Market surveillance activities

3.8.15 Article 94 - Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

3.8.16 Article 95 - Procedure for dealing with devices presenting an unacceptable risk to health and safety

3.8.17 Article 96 - Procedure for evaluating national measures at Union level

3.8.18 Article 97 - Other non-compliance

3.8.19 Article 98 - Preventive health protection measures

3.8.20 Article 99 - Good administrative practice

3.8.21 Article 100 Electronic system on market surveillance

3.8.22 CHAPTER VIII - COOPERATION BETWEEN MEMBER STATES, MEDICAL DEVICE COORDINATION GROUP, EXPERT LABORATORIES, EXPERT PANELS AND DEVICE REGISTERS

3.9 CHAPTER IX - CONFIDENTIALITY, DATA PROTECTION, FUNDING AND PENALTIES

3.10 CHAPTER X - FINAL PROVISIONS

3.10.1 Article 117 – Drug-device combination products

3.10.1.1 Which products are impacted by this article?

Combination products regulated as medicinal products.

3.10.1.2 What NB activities are required?

See MDP5000 Appendix.

For combination products marketed as medicinal product where the device part would have needed a CE certificate if it was marketed as a stand-alone, NB involvement is required to confirm compliance with applicable GSPRs but no CE certificate is issued. Instead a letter is provided to the Medicines Competent Authority reviewing the product.

Details to be confirmed once MHRA feedback is received.

3.11 Article 118 - Amendment to Regulation (EC) No 178/2002

3.11.1 Article 119 - Amendment to Regulation (EC) No 1223/2009

3.11.2 Article 120 - Transitional provisions

3.11.2.1 What is the transition period for the MDR?

The new European Medical Devices Regulation was published in the Official Journal of the European Union on 5th May 2017. The Regulations will enter into force on May 25th 2017, marking the start of the transition period for manufacturers selling medical devices into Europe.

The MDR, replaces the Medical Devices Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC), and has a transition period of three years. Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new requirements.

Article 120 of the Regulation states a number of transitional provisions, and should be referred to for more detail.

The CAMD – Transition Workgroup has developed Q&As for the MDR and IVDR. These have been available on their website since Q1 2018.

3.11.2.2 Does Article 120(4) apply to Class I medical devices under the MDD which are to become class IIa or above under the MDR?

Article 120 applies to all classes of devices. Class I devices under the MDD do not require NB involvement or certification. If the device is upclassified to class IIa under the MDR, a certificate from a NB under the MDR will be required to allow placing on the market after 26 May 2020.

3.11.2.3 What is the compliance date for Class Is? Is this the same as Class I? In which case, would a MDR certificate need to be in place that covered sterilization prior to May 2020?

The timeline for compliance to MDR are identical for all classifications. MDD certificates can be issued or renewed up until 26 May 2020 and become void at expiry or 27 May 2024 whichever is sooner. MDR certificates can be issued once the Notified Body is designated under MDR. See Article 120 for details.

3.11.2.4 How would the requirement that the device was "placed on the market" prior to May 2020 be interpreted for software (we are thinking that this could mean when the relevant version of the app is placed in the app store to be generally available or when it is provided to individual customers)?

An app store is an on line shop where you can make a purchase or a selection free of charge and instead of waiting for delivery (as with hardware) obtain direct access to the product via a download.

After May 2020 no further downloads should be permitted unless covered by a valid MDD certificate in which case they could be downloaded until at the latest 27 May 2025.

Software updates e.g. to fix bugs, would be permitted unless it is considered that the update changes the function or intended purpose of the software device in which case the update would be considered a device and the above rules would apply.

Even if the app store was a third party and based in the EU they would not be permitted to provide the product in unlimited numbers with no time bound requirement and so the above would apply.

3.11.2.5 If devices are upclassified by the MDR can they still remain on the market under the MDD until 2024?

If they have valid certification, they can follow the provisions of Article 120.

For devices that have no certification (Class I reusable, Class III custom made implants ...) they must obtain certification by the date of application.

3.11.2.6 Can a manufacturer have the same device covered by both MDD/AIMDD and MDR certificate until 24May2024?

Manufacturers are allowed to have MDD and MDR scopes covering the same devices. However, they will need to clearly trace each device/batch to either the MDD or MDR corresponding certificates.

A single device/device batch can only be covered by MDD or MDR certificates, not both.

3.11.2.7 Can a manufacturer add a new device to a MDD FQA/PQA certificate after 26 May 2020 if there is no significant difference in intended use and technology (ie under MDD no TF review would have been required)?

No. The provision of Article 120 are intended for devices already certified prior to 26 May 2020. New devices will require MDR certification application via appropriate route of conformity.

3.11.2.8 Can a manufacturer add a new size to a device under MDD certification after 26 May 2020 without triggering the need for MDR certification?

No. This would be considered a design change to introduce a new model/variation and would trigger requirement for MDR certificate.

3.11.2.9 If a manufacturer has MDD Certification for 3 years after the Date of Application of the MDR, can this manufacturer continue to manufacture medical devices with CE label according to the old MDD until the Certification runs out?

Labelling for devices placed on the EU market under the MDD must meet MDD requirements.

3.11.2.10 Can a manufacturer change subcontractors or EU rep after the date of application?

Changes to subcontractors on MDD certificates after the date of application may or may not trigger the requirement of Article 120 to require MDR certification depending on the specific situation.

Changes may require a MDD review as a significant change even if upgrade to MDR is not mandatory.

Change to EU rep is unlikely to trigger the need to upgrade to MDR, however the manufacturer should note the requirements for economic operators in Article 120 that apply to MDD certificate holders.

Scheme managers should follow MDP4901.

3.11.2.11 What type of changes will/will not trigger the Article 120 requirement to apply for MDR certification?

All cases will require review on case by case basis to make accurate decision. Some changes may be considered significant and require review under the MDD even if the need for MDR certification is not triggered.

Changes that will require MDR certification

Design

- Intended Use
- New clinical claims

Changes that may require MDR certification

- Subcontractors
- Material suppliers

Changes that will likely not require MDR certification

- Limitation of the intended purpose

- Design changes related to corrective actions, if assessed and accepted by the Competent Authority

Scheme managers should follow MDP4901.

3.11.2.12 Do devices with MDD certification have to meet the labelling requirements of the MDR after the date of application?

No, labelling requirements are not specified by Article 120.

3.11.2.13 Per the PMS requirements of Art 120 is a PSUR and SSCP required for MDD certified devices?

Yes, a PSUR is required, the PSUR will not be uploaded to EUDAMED. BSI will audit PSUR requirements during audits.

SSCP is not required.

3.11.3 Article 121 – Evaluation

3.11.4 Article 122 - Repeal

3.11.5 Article 123 - Entry into force and date of application

3.11.5.1 What happens if EUDAMED is not fully functional at the DoA? How does this affect the application of obligations and requirements of the MDR that relate to EUDAMED?

Art. 123 para 3 d MDR:

The different Articles listed in Art. 123 para 3 d (= dealing with e.g. the registration of devices and economic operators, clinical investigations, notified bodies, vigilance, post-market surveillance, market surveillance) are not fully postponed with regard to their application but generally remain applicable from the DoA. However, their application is postponed as far as the obligations and requirements within these Articles relate to EUDAMED (which is not fully functional yet). To that extent they shall apply from the date corresponding to 6 months after the date of notice of full functionality.

Meanwhile (until EUDAMED is fully functional) the corresponding provisions of the Directives regarding exchange of information continue to apply.

The principle is that the derogation applies to the electronic exchange of information/upload to EUDAMED. If the derogation is applicable this does not necessarily mean that the information itself does not need to be prepared/exchanged. This exchange of information e.g. reports will have to be done by other means in lieu of exchange via EUDAMED (Directives regime). The underlying idea behind this paragraph was to ensure compliance with the new obligations and requirements via the “old” systems as far as possible.

The actual practical implication of this concept with regard to the different Articles listed in Art. 123 para 3 d MDR needs a closer look and further guidance, which is in progress.

Art. 123 para 3 e MDR:

For the application of Art. 29 para 4 MDR and Art. 56 para 5 MDR in the case that EUDAMED is not fully functional in time, see question 20 and 21.

Ref CAMD Transition Sub Group FAQ v1.

4 ANNEXES

4.1 ANNEX I - GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

4.1.1.1 Can you confirm the essential requirements (ERs) list are being replaced with the general safety and performance requirements (GSPRs)?

Yes, GSPRs are the equivalent of the MDD ERs in the MDR.

4.1.1.2 How do we know how GSPRs and ERs relate to each other?

It is the manufactures responsibility to assess how their device meets each of the ERs under MDD and GSPRs under MDR. Manufactures may find this guidance useful during their assessment.

https://www.bsigroup.com/globalassets/meddev/localfiles/en-gb/documents/bsi-mdr-mapping-guide.pdf

4.1.1.3 Do we have a specific template for GSPR checklist?

No BSI does not provide templates for manufacture's quality system documents.

4.1.1.4 For General Safety and Performance checklist, do you anticipate that will be similar to the Essential Requirements checklist that references relevant documents? Or, are we expected to provide a summary rationale for each GSPR in addition to referencing relevant reports?

Annex II, particularly section 4 covers requirements for GSPRs. There is no requirement for a checklist. However, there are requirements for documented evidence of conformity and precise

traceability to evidence supporting compliance. If a checklist format is used it must meet these types of requirements.

4.1.2 CHAPTER I - GENERAL REQUIREMENTS

4.1.2.1 With reference to Annex I, Chapter I, 4 "Manufacturers shall inform users of any residual risks.", does this mean literally all residual risks?

The manufacturer should determine and justify the residual risks that require communicating to the user in the information supplied.

The MDR has several specific requirements that require consideration by the manufacturer for example but not limited to GSPR 10.4.5, 23.1, 23.4.

In addition, the manufacturer should disclose any residual risks that could potential impact on the safety and performance of the device. Residual risks for example the manufacturing process that have no impact on the final device safety and performance may not be required. The manufacture should determine this and justify it in the technical documentation.

4.1.3 GSPR 1

4.1.3.1 The standards for the evaluation of mechanical performance have changed since a device has been on the market. Can safe performance be demonstrated through the analysis of PMS data or does it need to be re-tested following the new standard?

It will depend on the nature of the PMS data. Typically, stating lack of complaints is considered insufficient however targeted PMS specifically collecting data on mechanical performance may be relevant.

4.1.4 GSPR 2

4.1.4.1 Where is the term "benefit-risk ratio" defined?

"Benefit-risk ratio" is not defined in the MDR definitions.

The MDR defines "benefit-risk determination" in Article 2 (24), "risk" in Article 2 (23) and "clinical benefit" in Article 2 (53)

(53) 'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health;

(23) 'risk' means the combination of the probability of occurrence of harm and the severity of that harm;

(24) 'benefit-risk determination' means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

4.1.5 GSPR 3

4.1.5.1 Is ISO 14971 prescribed by the MDR?

The MDR does not prescribe ISO 14971. It requires the manufacture have a risk management process in various parts of the text. ISO 14971 is the state of the art standard for risk management.

Many of the words from EN ISO 14971:2012 (Annex Z) have appeared in the MDR Annex I Safety and Performance Requirements.

4.1.6 GSPR 4

4.1.7 GSPR 5

4.1.7.1 We assume that following the usability engineering process contained in EN62366-1:2015 (Application of usability engineering to medical devices), including Annex C (Evaluation of a User Interface of Unknown Provenance), is sufficient to demonstrate that potential use errors are identified and mitigated as required by MDR. Does BSI concur?

-

BSI will not be able to answer until this standard is harmonized. BSI will expect manufactures to consider available state of the art guidance regardless whether it has been specifically ratified against the MDR.

4.1.8 GSPR 6

4.1.8.1 How should manufacturers define lifetime of the device? Functional lifetime such as until tissues heal with a permanent implant like a screw, or the length of time the implant remains in the body even if no clinical effect. Should companies do both? What is the requirement for PMCF throughout the lifetime?

BSI consider lifetime to be the whole time from point of use to disposal. PMCF may be required for this whole time. PMS will be required for the whole lifetime.

4.1.9 GSPR 7

4.1.10 GSPR 8

4.1.11 GSPR 9

4.1.12 CHAPTER II - REQUIREMENTS REGARDING DESIGN AND MANUFACTURE

4.1.13 GSPR 10. Chemical, physical and biological properties

4.1.13.1 What is the expectations regarding special substances such as CMR/Endocrine disrupting/animal tissue etc? Do manufacturer have to test to demonstrate these substances are not present?

The manufacturer needs to make an assessment to determine what is required in order to meet the requirements of the MDR which may vary from device to device.

4.1.14 10.3

4.1.14.1 Can manufacturers design a device to deliver a medical substance for off label use?

The requirement includes the statement “That the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.” This requirement could not be met if using the medicinal substance for an off label use.

4.1.15 10.4

4.1.15.1 Does 10.4.1 apply to devices intended to only remove substances or fluids from the body?

A device that is intended to only remove substances and fluids form the body may still inadvertently introduce such things back into the body. If such risk of this is possible for the device, then BSI would consider this GSPR to be applicable.

4.1.15.2 What are BSI’s expectations regarding harmonization with RoHS for active implantable devices or additional considerations related to REACH, carcinogenic, mutagenic, toxic, and biocidal material exclusions?

BSI does not have any additional information to provide at this time.

4.1.15.3 Does the new wording of GSPR 10.3 have to be interpreted as "off-label use of medicinal products" is not permitted under MDR?

GSPR 10.3 states "compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use."

It is BSI current interpretation that medicinal products intended for use with a given device have to be used within their approved indications and in line with their Marketing Authorisation.

It therefore appears difficult to promote the off-label use of a medicine with a device and still comply with GSPR 10.3.

4.1.16 GSPR 11. Infection and microbial contamination

4.1.16.1 Is there a greater emphasis on cleaning and disinfection validation documentation, especially considering the establishment of the new Class 1 Reusable classification?

It is BSIs opinion that the requirements are similar but the Notified Body's involvement in conformity assessment has been expanded in the area of reusable devices.

GSPR 11.4

4.1.16.2 SPR 11.4 states– "It shall be ensured that the integrity of that packaging is clearly evident to the final user". We would like to clarify if "do not use if packaging is damaged" is on the package, is this sufficient? If some other indication is required, please provide additional feedback.

BSI is not aware of another available indicator to demonstrate package integrity. Visual inspection by the end user is assumed and defined in the IFU, as well as the label symbols. Integrity should be ensured through all aspects of the device life cycle including handling, storage, and delivery (also clarified in ISO 13485).

Further information in our Whitepaper on Annex I: https://www.bsigroup.com/en-GB/medical-devices/resources/whitepapers/

4.1.17 GSPR 12. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.

4.1.18 GSPR 13. Devices incorporating materials of biological origin

4.1.18.1 GSPR 13 is titled "Devices Incorporating materials". Does this mean it only applies to devices that contain the material and not to devices which utilise such material in the manufacturing process?

No. GSPR 13.1, 13.2 and 13.3 clearly state the word "utilise" for each requirement therefore these GSPRs apply to "utilisation" of such material eith as part of manufacturing and/or as part of the final device.

4.1.19 GSPR 13.1

4.1.19.1 What happens if two competent authorities disagree if a product containing tissue of human origin is covered under the MDR?

This may need to be elevated to EU Commission level for arbitration. Article 51 covers the topic of classification disputes.

4.1.20 GSPR 13.3

4.1.20.1 Plant Based Derivatives: Scope of 13.3 – clarification regarding use of plant based derivatives. Is this intended to be derivatives used for medicinal purposes? For example – we may have plant based derivatives in place of tallow derivatives in manufacturing processing aids. These are not intended to have any impact on health or intended use. Confirming these do not fall within the intent of SPR 13.3.

BSI does not expect this to apply to some plant derivatives such as natural rubber latex. Examples in the scope of SPR 13.3 included recombinant protein produced by bacteria. Further clarification and confirmation should be sought from animal tissue experts regarding any specific examples or concerns.

4.1.21 GSPR 14. Construction of devices and interaction with their environment

4.1.22 GSPR 15. Devices with a diagnostic or measuring function

4.1.23 GSPR 16. Protection against radiation

4.1.24 GSPR 17. Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

4.1.25 GSPR 18. Active devices and devices connected to them

4.1.26 GSPR 19. Particular requirements for active implantable devices

4.1.27 GSPR 20. Protection against mechanical and thermal risks

4.1.27.1 The old ER 12s were specific to devices connected to an energy source, there are now SPR 20 and seemingly applicable to ALL devices?

GSPR is applicable to all devices however the manufacturer should review each of the indivi9dual requirements within GSPR 20 and consider whether they bare applicable or not. If not applicable the manufacture should document their justification for this conclusion.

4.1.28 GSPR 21. Protection against the risks posed to the patient or user by devices supplying energy or substances

4.1.29 GSPR 22. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

4.1.30 CHAPTER III - REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE

4.1.31 GSPR 23. Label and instructions for use

4.1.31.1 Do labels have to be translated (eg product descriptions) into every community language or if labels in English could the IFU have the information in all the other languages?

See Annex II, 2 the requirement for labels and IFU is that the information is “in the languages accepted in the Member States where the device is envisaged to be sold.

4.1.32 GSPR 23.1. General requirements regarding the information supplied by the manufacturer

4.1.32.1 Per GSPR 23.1 "Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following:" Does this mean labels and IFU have to be on the website?

BSI believes information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate has to be available on the website, not the full IFU. This interpretation may change in the future as BSI receives further information from the EU Commission and the CAs.

4.1.32.2 The second sentence of Annex I, sect 23.1 says "such information" shall be on the website. However, the first sentence talks about information twice. Does "such information" refer to "the information needed to identify the device and its manufacturer"? Or to "safety and performance information"? Or to both information?

Both.

4.1.33 GSPR 23.2. Information on the label

4.1.33.1 If a product has reduced or removed nanomaterials through cleaning steps in the manufacturing process, does the product labeling still need to include the symbology to indicate the potential risk or is this intended for products that only use nanomaterials as an intentional design element?

The MDR does not have explicit requirements for labelling of nanomaterials.

The manufacturers risk management documentation should determine the requirements for residual risks that require disclosure in the information supplied by the manufacture in order to meet GSPR 23.

4.1.34 GSPR 23.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging')

4.1.35 GSPR 23.4. Information in the instructions for use

4.1.36 GSPR 23.4(b)

4.1.36.1 What is the difference between intended use and indications for use? Where are these defined?

Article 2

(12) 'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;

Indications for use are not defined in the MDR

Indications of use is generally understood to mean a condition which makes a particular treatment or procedure advisable

4.1.37 GSPR 23.4(c)

4.1.37.1 4.1.11.1 What the expectations of "(c) where applicable, a specification of the clinical benefits to be expected?"

Clinical benefits shall be supported by clinical evidence. Clinical benefits should be described with relevant and specified clinical outcome parameters and the success rate for achieving the outcome parameters.

For further details, see the definitions in the MDR 2017/745, Article 2:

(51) 'clinical evidence' means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer;

(52) 'clinical performance' means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer;

(53) 'clinical benefit' means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health;

For example, for a hip replacement, the specification of clinical benefits would not be "treat osteoarthritis" or "replace painful joint", but would specify expected outcomes and potentially size of expected treatment effects for example range of motion, pain reduction, survivorship, etc.

4.1.38 GSPR 23.4(t)

4.1.38.1 23.4t "in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the

general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra- indications, undesirable side-effects and risks relating to overdose;" Does this apply to absorbable device such as sutures and meshes?

BSIs interpretation is this refers to devices cover under Rule 21 of Annex 8.

4.1.39 GSPR 23.4(u)

4.1.39.1 Is a full list of all materials and substances present in the device required to fulfil the requirement?

Yes, a full list of materials and substances to which the patient can be exposed to. This could include aspects such as name, composition, applicable standards etc.

4.1.40 GSPR 23.4(aa)

4.1.40.1 What does "information to be supplied to the patient with an implanted device in accordance with Article 18;" mean?

BSIs interpretation would be that this is referring to Article 18(1)

1.The manufacturer of an implantable device shall provide together with the device the following:

(a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

(b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;

(c) any information about the expected lifetime of the device and any necessary follow-up;

(d) any other information to ensure safe use of the device by the patient, including the information in point (u) of Section 23.4 of Annex I.

BSI does not believe that device specific information (Lot number, Serial Number) would be required in the IFU.

The information provided should be consistent with that provided by the manufacturer in order to conform to the Article 18 requirements.

4.2 ANNEX II - TECHNICAL DOCUMENTATION

4.2.1.1 Is there a specific format required for technical documentation? Is there a best practice guideline document for completing technical documentation under MDR?

The MDR does not have specific requirements for format beyond what is detailed in Annex II

"The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex."

and Annex III

"The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with Articles 83 to 86 shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements described in this Annex."

BSI does not prescribe the format of technical documentation.

BSI does have some requirements in terms of file size that can be submitted electronically and preferences to allow easier review (pdf, OCRed, single document, bookmarked). Refer to MDP4140 and https://www.bsigroup.com/globalassets/meddev/localfiles/en-gb/documents/bsi-md-mdr-best-practice-documentation-submissions-en-gb.pdf

The manufacturer may wish to consider Annex II and III of the MDR as well as guidance published by IMDRF (www.imdrf.org) on STED format.

4.2.1.2 Would IMDRF/STED format be accepted for the technical file?

Yes, provided that all aspects listed in Annex II and III are covered.

4.2.1.3 Do you expect the Annex II Technical Documentation and the Annex III Technical Documentation to be contained under a single 'document', or under two separate documents?

Either option would be acceptable.

4.2.1.4 Is it acceptable to submit only English SSCP, IFUs etc?

BSI require all technical documentation to be in English for review. BSI QMS auditors will include confirmation that manufacturers have appropriate translations procedures during QMS assessments.

4.2.1.5 *Is the Risk Benefit Profile expected to be a separate document or contained within CER/RMF?*

Annex II requires

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner and shall include in particular the elements listed in this Annex.

Furthermore, it requires under section 5

The documentation shall contain information on:

(a) the benefit-risk analysis referred to in Sections 1 and 8 of Annex I, and

(b) the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.

The MDR does not prescribe how this is documented.

4.2.1.6 How would you go about defining requirements for a self-assessed Technical File (for a non-sterile, non-measuring, non-reusable Class I device)?

The requirements for technical documentation in the MDR apply to all classifications.

4.2.1.7 For certification under the MDR will all Class IIa and IIb (non-implantable) be technical files reviewed against the MDR or will they be sampled?

See Annex IX section 2.3, Technical Documentation assessment will be performed on sample(s) selected on a representative basis.

Internal comment

BSI will treat IIa and IIb non-implantable the same as currently under the MDD. The term “category” (MDR) and “sub-category” (MDD) for IIa devices will be considered synonymous.

4.2.1.8 For each group or category to be included in the scope of a Quality System Certificate, one file within that category or group would need to be sampled. Is the Technical Documentation assessment for Class IIb implantable devices based on a representative sample of the generic device group?

The language in the MDR indicates that Class IIb implantable devices will need a detailed Technical Documentation review analogous to a Class III device under the current MDD. Hence sampling will not be possible.

See article 53(4): However, for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in Section 4 of Annex IX shall apply for every device.

4.2.1.9 *Are five year renewals for Class III devices subjected to Commission review, or does this just apply to the original application?*

Five year renewals are not subject to clinical evaluation consultation with the Commission, assuming there were no substantial changes made to the device which may require a Commission review.

4.2.1.10 *Have the requirements for Technical Documentation for Class IIb products that deliver medicines increased?*

The language in the Regulation suggests a more robust set of Technical Documentation similar to a Design Dossier under the current MDD/AIMD. Class IIb active devices intended to deliver medicines are subject to the clinical evaluation consultation procedure (Article 54 and Annex IX section 5.1) and can also be subject to scrutiny as described in Annex IX or Annex XI of the MDR.

4.2.1.11 *Am I able to self-certify devices under the MDR?*

It is possible to self-certify Class I, non-measuring, nonsterile, non-reusable products under the MDR.

4.2.1.12 *What documentation will I need to provide for a Class I reusable device with regards to cleaning?*

Along with the cleaning instructions and associated validations, Notified Body assessment will also include other areas such as disinfection, sterilization, maintenance, functional testing. For more information, see Article 52 of the MDR.

4.2.1.13 *What would be BSI's expectation on how to document user training (if required during the roll-up of the approved device) in the Technical Documentation?*

The manufacturer should include all quality system documentation related to the requirements for user training needed to meet the MDR.

This may include items such as (but not limited to)

- IFU
- Label
- Brochure
- Training manual/course materials/examinations/ToUs
- Qualifications/requirements to be able to use for training and use independently after training
- Any restrictions on who can use the device
- User requirements that must be met before the user uses the device
- Use risk assessment
- Ergonomics assessment
- Post market user feedback

4.2.1.14 *For off the shelf products where there is no access to design files what recourse will manufacturers have? For example, for currently marketed kits using off the shelf accessories.*

The manufacturer is responsible for having complete technical documentation per Annex II & III.

4.2.1.15 *With reference to Annex II, 2 "a complete set of labelling", does this have to be physical present in the technical file or is it sufficient to reference the location of such labelling? Are technical drawings of the labelling a requirement or can this be in the form of a controlled physical copy of the labelling and or IFU?*

The manufacturer will need to provide to the Notified Body, evidence of how they meet GSPR 23s and the Notified Body may have to retain these on file. The manufacturer must therefore be capable of providing these files. BSI prefers electronic pdf format files.

4.2.1.16 *Per Annex II Section 1.1.(h), the Device Description included in the Technical Documentation shall contain, a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;*

What is BSI's expectation regarding the scope?

Does BSI expect for this description to include other devices manufactured by us, and competitor's devices?

All accessories, devices and other products which are not devices whether manufactured by the legal manufacturer or not.

4.2.1.17 How do manufacturers determine acceptable minimum label/IFU languages for each member state under MDR?

The manufacturer should contact the Competent Authorities for the member states of interest to ask them for their requirements.

4.2.1.18 Per Annex II, 6.1 the documentation shall contain " (b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular: — the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user; — physical, chemical and microbiological characterisation;". Later it says "Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service;". For Legacy devices being certified under the MDR would a full ISO 10993-1 chemical characterization be required?

Relevant biological compatibility evaluation and or testing per the requirements of the MDR, utilising state of the art standards and guidance is required. Whereby the manufacturer has chosen not to follow or to follow only parts of these documents the manufacturer must document a suitable justification for the approach they have taken.

4.3 ANNEX III - TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

4.3.1.1 Should the PMCF report include proactive or reactive data or both?

Both. Annex III defines the requirements for PMS Technical Documentation. The Annex requires a PMS plan that includes both proactive and reactive sources of PMS data. Requirements for reporting are further covered by Article 85 and 86. Both Articles require reports that include all data from the PMS plan.

4.4 ANNEX IV - EU DECLARATION OF CONFORMITY

4.4.1.1 What is the difference between the old and new format of Declaration of Conformities?

The MDR sets out specific requirements for DoC content not previous detailed in the MDD. See Annex IV for details.

4.4.1.2 When must the Declaration of Conformity be created? After the device has been developed and tested but before market launch?

The DoC must be created and sign prior to the device being place on the market. The DoC cannot be signed until all conformity assessment processes have been completed.

4.4.1.3 Per Annex IV, 6 the DoC shall contain "A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;". After the Date of Application of the MDR will BSI expect the DoC to contain a reference to the MDD if we still have MDD certificates?

Yes, BSI expects reference to MDD.

4.4.1.4 Can manufactures claim that a specific batch meets the requirements of both MDD and MDR so that the requirement for traceability to particular batch is not necessary and then have one DOC that covers both MDD and MDR?

Yes, as long as the DoC is clearly worded and meets the requirements under MDD and MDR for content. Manufactures may also wish to consider ISO 17050 and the New Approach Blue Guide.

4.5 ANNEX V - CE MARKING OF CONFORMITY

4.6 ANNEX VI - INFORMATION TO BE SUBMITTED UPON THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS

4.7 ANNEX VII - REQUIREMENTS TO BE MET BY NOTIFIED BODIES

4.8 ANNEX VIII - CLASSIFICATION RULES

4.8.1.1 Will a similar document to MEDDEV 2.4 be issued for the MDR?

It is BSIs opinion that there will be either a new similar guidance document or new version of the current one for the MDR. Previous decisions will probably remain the same unless contradicted by the MDR text.

Based on our current information, a new Borderline manual will be issued for the MDR.

4.8.2 CHAPTER I - DEFINITIONS SPECIFIC TO CLASSIFICATION RULES

4.8.3 CHAPTER II - IMPLEMENTING RULES

4.8.4 CHAPTER III - CLASSIFICATION RULES

4.8.5 NON-INVASIVE DEVICES

4.8.6 Rule 1

4.8.7 Rule 2

4.8.8 Rule 3

4.8.9 Rule 4

4.8.10 INVASIVE DEVICES

4.8.11 Rule 5

4.8.12 Rule 6

4.8.13 Rule 7

4.8.14 Rule 8

4.8.15 ACTIVE DEVICES

4.8.16 Rule 9

4.8.17 Rule 10

4.8.18 Rule 11

4.8.19 Rule 12

4.8.20 Rule 13

4.8.21 SPECIAL RULES

4.8.22 Rule 14

4.8.22.1 What is the impact of the removal of "liability to act"? Will all devices incorporating a medical product that has an ancillary action be class III?

BSI are, of course, aware of the removal of the liability to act clause, but unfortunately it is too early to be able to give a BSI position on this. BSI are waiting on an updated borderline manual which the European borderline committee have said they are working on to provide further guidance in this area.

In general, the MDR will result in more class III devices, but some examples may still be on the borderline. We would anticipate, if the guidance doesn't make things clear an increase in the number of classification enquiries to a Competent Authority prior to certification under the MDR.

4.8.23 Rule 15

4.8.24 Rule 16

4.8.25 Rule 17

4.8.26 Rule 18

4.8.26.1 Will exclusions under MDD for tallow and tallow derivatives still apply under MDR?

BSI expect these to be upheld though this is not yet defined in any guidance for the MDR.

4.8.27 Rule 19

4.8.28 Rule 20

4.8.29 Rule 21

4.8.30 Rule 22

4.8.31 Questions on Specific Device Types

4.8.32 Sutures

4.8.32.1 For devices used in spine, the MDR currently classifies them as class III. Does this include sutures used in spinal surgeries?

Per Annex VIII

5.3. Rule 7 All surgically invasive devices intended for short-term use are classified as class IIa unless they:

— are intended specifically for use in direct contact with .... the central nervous system, in which case they are classified as class III;

5.4. Rule 8 All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:

— are intended to be used in direct contact with ..... the central nervous system, in which case they are classified as class III;

Sutures are not an exception to these rules.

4.8.33 Ophthalmic devices

4.8.33.1 Will implantable ophthalmic devices (IOL, CTR etc.) that are currently Class IIb under MDD be up classified to Class III?

Ophthalmic implants classified IIb under rule 8 of the MDD are not likely to change classification under MDR unless other special rules apply.

Does Annex VIII, 3.6 mean that daily wear contact lenses will be up classified from Class IIa to Class IIb?

BSI does not believe that these devices will be up classified to class IIb due to this clause. Extended wear lenses indicted for use for 30 days without a wash out period will continue to be Class IIb.

4.8.34 Software

4.8.34.1 For the reclassification of software, is the term "may" result in death or irreversible damage interpreted as the likelihood?

Clarification is required from the EU Commission and Competent Authorities on the intent of this text in Rule 11 of Annex VIII.

4.8.34.2 When will software be considered "software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes", since this could be interpreted very broadly to apply to many software medical devices

- Rule 10 under the MDD refers to active devices intended for diagnosis are in class IIa.....if they are intended to allow direct diagnosis or monitoring of vital physiological processes..... "To allow direct diagnosis" does not mean that it has to be the only diagnosis tool used to come to the decision. It could be by itself or it could also provide decisive information for the diagnosis along with other indicators.
- The above rule applied also to software as it is an active device
- Rule 11 in the MDR more explicitly considers Software (catching up with the times when software was not a big issue when the MDD was written) on its own and clarifies the "direct diagnosis" definition to include software that is used to provide decisive information, either

alone or with something else to make a decision on a diagnosis. I do not think this is such a big change but more of a clarification. It is very unlikely that a clinician would rely only on one source of information for a diagnosis.

- What is more significant is that it now also includes a decision for therapeutic purposes but I suppose this would lead on from a diagnosis decision to a treatment decision.
- The most significant change is the increase of classification to class III for software that makes a decision the impact of which may cause death or an irreversible deterioration of a person's state of health. How this will be determined is very open to interpretation and will require clinical input.

4.8.34.3 Rule 11 of the MDR provides that all software that is intended to monitor physiological processes or provide clinical decision support, is classed as Class IIa (or higher). We understand that this is – and was intended to be – a major change from the current regime under the Directive, and will increase the regulatory burden for software. Under Article 2(4), software is considered to be an active medical device. However, is there any rationale why the MDR treats software under Rule 11 (software…. "used to take decisions with diagnosis or therapeutic purposes") more strictly than other "active medical devices" under Rule 10 ("Active devices … intended to allow direct diagnosis […]")?

- Software is considered an active device under both the MDD and MDR. It is more explicit in the MDR.
- Rule 10 under the MDD refers to active devices intended for diagnosis are in class IIa.....if they are intended to allow direct diagnosis or monitoring of vital physiological processes..... "To allow direct diagnosis" does not mean that it has to be the only diagnosis tool used to come to the decision. It could be by itself or it could also provide decisive information for the diagnosis along with other indicators.
- The above rule applied also to software as it is an active device
- Rule 11 in the MDR more explicitly considers Software (catching up with the times when software was not a big issue when the MDD was written) on its own and clarifies the "direct diagnosis" definition to include software that is used to provide decisive information, either alone or with something else to make a decision on a diagnosis. I do not think this is such a big change but more of a clarification. It is very unlikely that a clinician would rely only on one source of information for a diagnosis.
- What is more significant is that it now also includes a decision for therapeutic purposes but I suppose this would lead on from a diagnosis decision to a treatment decision.
- The most significant change is the increase of classification to class III for software that makes a decision the impact of which may cause death or an irreversible deterioration of a person's state of health. How this will be determined is very open to interpretation and will require clinical input.

4.8.35 Vascular devices

4.8.35.1 The MDR classification rules includes the arcus aortae and aorta descendens to the bifurcatio aortae in the definition for central circulatory system. Most of our catheters/PTA devices are indicated for use in the iliac artery, however an 'up-and-over' approach is used for placement,

which means they do come into direct contact with the aortic bifurcation. Under Rule 7, they were previously classified as IIa devices. Because our devices are indicated for use in the iliac artery we would propose these devices would remain IIa. These device has a long history of use on the market and there is no know change in the risk profile. Can you please let us know BSI's position on the classification rule change?

Due for discussion by the borderline group.

4.8.35.2 *Under the current MDD there some vascular devices (guide catheters, balloon dilatation catheters, guidewires and others) that are used to access the peripheral arteries by the contralateral approach (they are inserted into a femoral artery in one leg and access the femoral artery in the other leg). Hence the "come into contact with the aortic bifurcation". According to Rule 6, in the MDR:*

Due for discussion by the borderline group.

4.8.35.3 *"All devices intended specifically for direct contact with heart or central circulatory system now class III similar to devices in contact with central nervous system" Would these devices now be Class III?*

Although the descending thoracic aorta and the aortic bifurcation are part of the CCS under the MDD the V-team has taken a pragmatic approach and classified these as Class IIa as they are NOT specifically used to control, monitor, or diagnose nor correct a defect of the CCS. Going through the descending thoracic aorta or the aortic bifurcation is just a means of access. This would also apply to catheters that access the renal arteries.

Due for discussion by the borderline group. BSI would interpret these as Class III.

4.8.35.4 *Are Perfusion lines being reclassified?*

Due for discussion by the borderline group.

4.8.35.5 *Our device is Angioplasty balloon catheter and is class IIa. Is the classification changed for these devices?*

Due for discussion by the borderline group.

4.8.36 O&D Devices

4.8.36.1 Are spinal implants that were previously class IIb under MMD now class III under MDR?

Spinal disc replacement devices are now considered Class III per Rule 8 under the MDR. Implantable devices that contact the spinal column are also potentially class III. However, BSI consider that some devices fall under the exception wording 'components such as screws, wedges, plates and instruments' and could remain Class IIb if agreement is confirmed with CA's / EU Commission. For example, pedicle screw systems for fusion application and monoblock spinal cages are considered to fall under the screw and wedge exceptions. Further confirmation and guidance on this is currently being determined.

4.9 ANNEX IX - CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

4.9.1.1 We have FQA and DE certificates under MDD. Can we apply for MDR DE certs before upgrading our FQA to MDR?

Manufactures will have to have MDR FQA certificate in order to have a MDR product certificate. If transitioning products in phased approach or maintaining MDD certificates that may mean the manufacturer holds MDD and MDR FQA certs simultaneously.

4.9.2 CHAPTER I QUALITY MANAGEMENT SYSTEM

1.

4.9.2.1 Is there an expectation for Legal Manufacturers to be certified according to ISO 13485 under the MDR? Under MDD this was not necessarily the case.

The MDR does not prescribe use of ISO 13485.

The MDR does require that the manufacturer establish a quality system for many routes of conformity.

ISO 13485 is the state of the art standard for quality systems for medical devices. The MDR does require the manufacturer take into account the state of the art.

BSI expects that ISO 13485 will become a harmonised standard for the MDR.

4.9.2.2 Which parts of MDR are addressed by QMS compliance to ISO 13485:2016? What additional requirements must be considered?

There is a document being prepared that will assist with this CEN/TR 17223 Guidance on the relationship between EN ISO 13485: 2016 (Medical devices - Quality management systems - Requirements for regulatory purposes) and European Medical Devices Regulation and InVitro Diagnostic Medical Devices Regulation

In the meantime, there are various presentations / resources on the BSI website that may assist with this.

2.2

4.9.2.3 With reference to Annex IX, Chapter I, 2.2(c) what is meant by "identification of relevant legal requirements"?

The manufacturer is responsible for identifying, as part of their regulatory strategy, any and all legal requirements that need to be meet for their devices, for example which EU Directives and or Regulations apply to the device.

2.4

4.9.2.4 What is the definition of a significant change?

Referring to changes under conformity assessment annexes

Annex IX, 2.4, 4.10, 5.2(f), 5.31(d)

Annex X, 5

It is BSIs interpretation that this will be treated the same as under the MDD. The manufacturer is responsible for defining a process to identify substantial changes to the quality system, the device range covered, changes to the apporved device and changes involving particular substances.

Referring to Article 120, 3

The MDR does not define "significant change".

BSIs current interpretation would be that any changes to design or intended use currently considered "significant" under the MDD would be considered "significant" under MDR Art 120. Other types of "significant change" that do not impact design or intended use may be acceptable.

Introduction of a new device would be considered significant under Article 120 and require MDR certification following the appropriate route to conformity.

3.4

4.9.2.5 How often will BSI conduct UAVs for a manufacture with WET implants?

BSIs interpretation is that WET and non-WET devices will be treated the same for UAV sampling. For example, BSI will conduct UAVs for all IIb implants once every three years (MDP4102).

4.9.3 CHAPTER II - ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4.9.3.1 Will BSI QMS Auditors look at technical documentation during MDR assessments?

QMS auditors may sample technical documentation to verify its existence and as part of assessing processes. Technical auditors will review technical documentation to assess whether it meets the requirements and to assess safety and performance of the device under review. This is the same as under the MDD.

4.6

4.9.3.2 With reference to Annex IX,4.6

"4.6. The notified body shall verify that the clinical evidence and the clinical evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. That verification shall include consideration of the adequacy of the benefit-risk determination, the risk management, the instructions for use, the user training and the manufacturer's post-market surveillance plan, and include a review of the need for, and the adequacy of, the PMCF plan proposed, where applicable."

What should a manufacturer include with regard to the user training?

The manufacturer should include all quality system documentation related to the requirements for user training needed to meet the MDR.

This may include items such as (but not limited to)

- IFU
- Label
- Brochure
- Training manual/course materials/examinations/ToUs

- Qualifications/requirements to be able to use for training and use independently after training
- Any restrictions on who can use the device
- User requirements that must be met before the user uses the device
- Use risk assessment
- Ergonomics assessment
- Post market user feedback

5.2

4.9.3.3 Are new consultation dossiers required for our Class III devices containing medicinal substances under MDR?

BSI's current belief is that where the MDR requirements trigger the need for a medicinal substance consultation the process will be able to point to the consultation previously performed under the MDD.

BSI will need to review the previous consultation and confirm that it is still relevant given the time passed since the consultation was performed and that it still represents the state of the art. BSI will need to confirm with the Competent Authority that BSIs opinion following this review is acceptable.

The acceptability of this approach is part of ongoing discussions with the relevant authorities.

4.9.3.4 Our current understanding is that API sites do not need to be GMP compliant if significant quality controls are in place. Is this still the understanding under MDR?

BSI does not expect current understanding under MDD to change with MDR so this may be acceptable under certain circumstances.

4.9.4 CHAPTER III ADMINISTRATIVE PROVISIONS

4.9.4.1 "The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:" Does this mean 10 or 15 years after shelf life expiry?

No this does not mean after the shelf life. It means from the date the final device was placed onto the EU market. Note that quality management system standards may have additional requirements.

4.10 ANNEX X - CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

4.11 ANNEX XI - CONFORMITY ASSESSMENT BASED ON PRODUCT CONFORMITY VERIFICATION

4.11.1.1 Is TF review required for Annex XI

Yes.

Class IIa devices under Annex XI part B:

10.2. For class IIa devices the notified body shall assess, as part of the assessment referred to in Section 6.3, whether the technical documentation as referred to in Annexes II and III for the devices selected on a representative basis is compliant with this Regulation.

4.12 ANNEX XII - CERTIFICATES ISSUED BY A NOTIFIED BODY

4.12.1.1 Class IIb WET implants – does the intended purpose on the QMS certificate need to be as detailed as the IFU?

As per Annex XII 4(b), yes they should be the same.

(b) EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification, and, for class IIb devices, the intended purpose.

4.13 ANNEX XIII - PROCEDURE FOR CUSTOM-MADE DEVICES

4.14 ANNEX XIV - CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

4.14.1 Part A Clinical Evaluation

4.14.1.1 Will a new CER be required for MDR or can we use our current CER MEDDEV 2.7.1 rev 4 compliant CER?

There is no requirement for a “new” CER. The manufacturer will have to provide a CER that is in conformity with the requirements of the MDR.

4.14.1.2 What is BSI's timeline for creating clinical evaluation assessment report (Annex IX for class III and class IIb active products to deliver medicinal products) for sharing with the Commission / expert panel?

This will depend on the quality of the technical documentation provided.

4.14.1.3 Will I be required to perform testing to ISO 10993 for an equivalent device?

Possibly. It depends on how equivalent the subject and the comparator devices are from a biological perspective. Please also note that the MDR has separate stand-alone safety and performance requirements related to biological safety of the device which may also require compliance with ISO 10993.

4.14.1.4 Will the Periodic Safety Update Report (PSUR) need to be included in the Clinical Evaluation Report (CER)?

The MDR requires that the Clinical Evaluation is updated periodically based on Post Market Surveillance (PMS) data. However, inclusion of the PSUR in the CER is optional. The PMS data which the PSUR is based on should be used to update the CER.

4.14.1.5 Do the post-market reporting requirements apply to only Class III implantable products, or to all Class III and also to all implantable products?

BSI's interpretation is inclusive; that it applies to Class III devices and all implantable devices.

4.14.1.6 Do the Periodic Safety Update Report (PSUR) and Summary of Safety and Performance requirements (SSCP) have to be generated by individual device or can they be generated by device family?

This will need to be considered on a case-by-case basis. With regards to SSCP, Article 32 indicates that the Device Identifier is included in the SSCP. With regards to PSUR, the wording in Article 86 allows PSUR to be prepared per device and where relevant per category or group of devices. If such grouping were to occur, Notified Bodies expect that the rationale behind grouping the devices is clearly documented.

4.14.1.7 Can some aspects of literature review be considered active PMS?

Yes, some aspects

4.14.1.8 If publications are on the devices under review, however there are few details on actual sizes, actual materials or actual design features can the publication be included to support data on the actual devices.

Yes, it is possible to learn about safety and some aspects of performance. They may need to be more data to be sure about the materials and design feature specifics.

4.14.1.9 Can some aspects of a device clinical performance be covered by non-clinical data?

Yes, if there are prescriptive standards

4.14.1.10 Question Does MedDev 2.7.1 Rev 4 meet the MDR?

MedDev 2.7.1 Rev 4 has a scope to cover the existing Directives, however the requirements take a step in the direction of the MDR.

4.14.1.11 Does complaint/incident data on existing devices count toward clinical safety and performance?

Yes, some of this data can support safety, however an absence of incidents is not necessarily evidence of all aspects of safety and performance.

4.14.1.12 Is CER required through out of the life of the product like PMS?

Yes.

4.14.1.13 For CER and PMS Report, if there are competitor devices that have a different mode of action, different implant method, material, etc, how important or necessary is it to include and review the competitor devices in the literature search?

Article 61,3(c) states the information the clinical evaluation must be based on shall include “a consideration of currently available alternative treatment options for that purpose, if any.”

4.14.2 Part B Post-Market Clinical Follow Up

4.14.2.1 Can PMCF ever stop?

Yes, when there is evidence to cover the lifetime of the actual device under review.

4.14.2.2 What is BSI's expectation regarding the duration of pro-active post-market surveillance activities for an obsoleted device?

Lifetime of the device.

Article 83

2.The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime,

Annex XIV 5

PMCF shall be understood to be a continuous process that updates the clinical evaluation referred to in Article 61 and Part A of this Annex and shall be addressed in the manufacturer's post-market surveillance plan. When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

4.14.2.3 If necessary, how would we engage with BSI to confirm our PMCF assessment?

BSI cannot provide consultancy on PMCF plans. BSI will review PMCF plans and associated documents during initial and or surveillance audits and technical documentation reviews. The MHRA is open to discussion with manufacturers on suitability of clinical investigation plans, manufacturers may wish to contact them directly.

4.14.2.4 If a PMCF is necessary, is it acceptable to include the PMCF plan only at the time of application?

BSI will expect to see as well as the PMCF plan copies of proposed protocols for studies and other associated documents required to fully understand the PMCF proposal.

4.14.2.5 Can PMCF include a comparative study with competitor's device?

Annex XIV does not prohibit this.

4.14.2.6 Can proactive PMCF include the proactive analysis of retrospective data?

Annex XIV does not prohibit this.

4.14.2.7 What type of design changes would require PMCF? Although MEDDEVs technically do not provide guidance to MDR, will MEDDEV 2.12/2 still be considered state of the art guidance under MDR?

It is the responsibility of the manufacturer to determine whether PMCF is required or not.

It is BSI's opinion that current MDD guidance until updated for MDR or specifically covered by the MDR already can still represent the state of the art.

4.15 ANNEX XV - CLINICAL INVESTIGATIONS

4.16 ANNEX XVI - LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE REFERRED TO IN ARTICLE 1(2)

4.16.1.1 Can BSI confirm when the MDR applies to devices with no medical purpose? For devices that have both an intended purpose with a medical purpose and without a medical purpose that share common technical documentation, instructions for use etc how will BSI deal with an MDR application for the device with medical purpose if the CS has not yet been published?

Per Article 1

"2.This Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9, to the groups of products without an intended medical purpose that are listed in Annex XVI".

Until the CS has been published the MDR does not apply to products with no medical purpose and furthermore NBs will be required to be designated for these types of devices once the CS have been published.

If the manufacturer applies for MDR certification for a device that has a medical purpose it must meet the full requirements of the MDR with respect to technical documentation, particularly with regards to clinical evaluation.

4.17 ANNEX XVII - CORRELATION TABLE