BSI Medical Devices: Webinar Q&A

MDR Conformity Assessment Routes

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Use our MDR Conformity Assessment Routes guide, MDR Readiness Review and MDR Mapping Guide as you prepare for your transition to the Medical Devices Regulation.

We recommend regularly checking the European Commission website (https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en) for additional guidance that may be published in the future. The Commission website also allows a user to subscribe to a newsletter for any updates which can also be very useful.

Q&A

Q. What is the difference between custom-made Class III implantable devices and non-custom?
A. As per Article 2.3 of MDR, ‘custom-made device’ means any device specifically made in accordance with a written prescription of any person authorized by national law by virtue of that person’s professional qualifications which gives, under that person’s responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. If the classification of the custom-made device is Class III and it is implantable, then it becomes a custom-made Class III implantable device.

Q. How does a manufacturer take the SRN (Single Registration Number) to be compliant with UDI?
A. Manufacturers have to obtain their SRN number from their Competent Authorities once the EUDAMED system is live.

Q. Regarding the availability of UDI, the Declaration of Conformity and a lot of documents are linked with UDI. How will the conformity assessment be available?
A. The Commission website has several useful guidance documents related to UDI. Conformity assessments will be carried out without the UDI information. Manufacturers will be expected to comply with the UDI information as and when these systems become available.

Q. Do medical devices of Class I (Sterile or Measurable) need an involvement of a Notified Body and CE Certificate?
A. Yes; the involvement of the Notified Body will be limited to the sterility and the metrology aspects of such devices.

Q. Can you comment on QMS requirements for Class I devices?
A. All the general obligations described under Article 10 of a legal manufacturer would apply and those specified in Article 52.7 for Class I devices.
Q. Does QMS need to be in place for Class I devices? The regulation says that Class I devices don't need Notified Body involvement, so can we sign a Declaration of Conformity when the Technical File is ready?

A. Yes, it is correct that Notified Body involvement is not required for Class I (excluding Sterile, Measuring or Reusable surgical instruments) devices. However, manufacturers still have to meet all the general obligations described under Article 10, and requirements specified under Article 52.7 before signing the Declaration of Conformity.

Q. For Class Is or Im, how are the elements assessed? Via audit or file review? At time of submission or sampling at time of audit?

A. Class Is devices will need a QMS audit and a Microbiology audit; Class Im devices just need a QMS audit.

Q. Regarding procedure packs does Article 12 apply to bulk non-sterile components?

A. Article 12 refers to procedure packs in the MDD. The corresponding article under the MDR is Article 22. Both of these clearly state that the devices within the packs/kits should bear the CE mark.

Q. If we got a certificate under MDD in 2019 will it be continued after 2020?

A. If the MDD certificate validity extends beyond May 2020, the manufacturer can continue to place devices on the market based on that directive certificate. However, there are specific deadlines based on the types of certificates and additional requirements from the MDR which would still apply to devices under the MDD after the May 2020. Please refer to Article 120 transitional provisions for additional details.

Q. Do Class Is/Im/Ir devices require a PSUR document?

A. Class Is/Im/Ir do not have requirements for a PSUR; but Article 85 requires a Post Market Surveillance report to be prepared for Class I devices.

Q. For Class IIa, IIb and III devices – do we need PSUR as per MDR?

A. Yes. Please refer to Article 86 for additional information.

Q. Do we require a PSUR report at the time of application?

A. Under MDR, PSURs will only apply after the initial certification. Note that PSUR requirements may also apply to any devices that are still certified under MDD after 26 May 2020 due to the transitional provisions specified in Article 120.

Q. Where does the PRRC fit into the conformity assessment process?

A. Provisions related to PRRC will be assessed during the BSI QMS audits. Requirements for PRRC can be found in Article 15 of the MDR.
Q. Slide 8 shows that Article 117 Class III implantable drug/device combination devices require an MDR CE by 26 May 2020. Does this include drug eluting leads where the drug is used short term to reduce inflammation at implant?

A. Article 117 is specific and covers drug-device combinations that are covered by the medicines directive 2001/83/EC, but also contain a device portion/part. The manufacturer will have to determine whether drug eluting beads fall under the MDR or the medicines legislation. The 26 May 2020 date specified on slide 8 applies to the drug-device combinations that fall under Article 117, not device-drug combinations that fall under Article 52.

Q. What is the best conformity assessment route for software as a medical device company (e.g. IIa or IIb)?

A. All routes for any given classifications generally provide equivalent assurance of compliance and are equally burdensome – the manufacturer must choose a conformity route that best fits their needs. The classification of the software will depend on the intended use(s) of the software and the applicable rules within Annex VIII of MDR.

Q. What types of functionality would make software a medical device?

A. Any software that meets the definition of a medical device as per Article 2.1 will qualify as a medical device. Additional guidance is expected from the Commission in Q3/Q4 2019.

Q. How are manufacturers expected to apply conformity assessment and submit an MDR application for Notified Body assessment when we know (and have the disclaimer at the beginning of the presentation) things might still change regarding implementation?

A. Any applications made now will be assessed based on the current guidance available and understanding/interpretation of the requirements.

Q. Will BSI be accepting ISO 13485 certification as evidence of conformity to QMS requirements within the Annexes of MDR?

A. EN ISO 13485:2016 is not yet harmonized to MDR. However, it will be considered state of the art for meeting some of the QMS requirements specified within MDR. Note that MDR may contain some requirements over and above those specified within ISO 13485 and manufacturers will be expected to meet these requirements as well.

Q. Is there any update on when BSI Netherlands (2797) shall be designated under the MDR as the UK (0086) is?

A. BSI NL designation to MDR is expected early Q4.
Q. How will pre-filled syringes be classified under MDR?
A. Pre-filled syringes generally are covered by the medicines legislation 2001/83/EC. Manufacturer must evaluate whether Article 117 for drug device combinations may apply to such devices.

Q. Can the manufacturer choose the conformity assessment path within their classification?
A. Yes. However, they must ensure that the Notified Body they apply to has those conformity assessment annexes and the type of devices within their designation scope.

Q. Will there be a separate audit for QMS or will this be captured under Annex IX and technical documentation/surveillance audits?
A. BSI QMS audits will focus on the quality system elements. As a part of the audit, the technical documentation may be checked from a top level by the BSI QMS auditors to ensure that the underlying procedures and processes to generate the technical documentation are robust. However, in depth review of the technical documentation will be conducted separately by BSI Technical Specialists.

Q. If all technical documentation reviews will follow Annex IX section 4, will BSI issue a TD assessment certificate for every Class IIa and IIb WET TD that is sampled?
A. Class IIa and Class IIb WET devices will not be issued a technical documentation assessment certificate. However, the assessment itself will follow Annex IX section 4.

Q. Could you talk about Annex XVI. What comes in the scope?
A. Annex XVI covers devices without a medical purpose and explicitly lists the types of devices covered under the scope of MDR. Please refer to Annex XVI of MDR.

Q. What would be the class of a medical gases pipeline and accessories (valves, tubes, reducers, etc...)?
A. Please refer to Annex VIII of MDR for identifying the applicable classification rules and the resulting classification. Notified Bodies cannot offer advice on classification of medical devices.

Q. What will be a sterile audit, is it separate to QMS audit?
A. Devices that have sterility involved will require a separate microbiology audit in addition to the QMS audit. During the microbiology audit, all aspects related to establishing and maintaining the sterility of the devices will be covered.
Q. It is often mentioned clinical investigations are mandatory for Class III devices and implantable medical devices, however for Class IIa products is it mandatory to conduct a clinical investigation or could sufficient bibliographic data be sufficient?

A. For Class IIa devices, manufacturers may depend on literature if there is sufficient clinical evidence of safety and performance of the device for all the claimed indications for use. Please refer to Article 61 for further details.

Q. For legacy products Class III sterile implantable, will we be able to use clinical data generated for our initial registration or will we need to perform new clinical studies?

A. Article 61 specifies the requirements related to clinical evaluations for Class III implantable devices. Please refer to Article 61.6 for requirements related to devices that are already on the market under MDD/AIMDD.

Q. How is BSI keeping up with the publication of key guidance documents, common specifications etc.?

A. BSI has its own internal procedures/processes and nominated people who are responsible for checking to see if any new guidance documents are published, reviewing them and implementing them as required within BSI's systems.

Q. For Class III devices, Annex X (type examination route), could you please elaborate further on whether the Notified Body will be reviewing production quality assurance and production verification prior to launch of every device or it will be based on a periodic audit?

A. The Notified Body conformity assessment will depend on the route to conformity chosen – Annex X + Annex XI Part A or Annex X + Annex XI Part B. In the former, all the required QMS, Microbiology, Technical Documentation and Type testing activities will need to be completed prior to certification. In the latter, Annex X will be a one-off type test and technical documentation review, whereas the assessment under Annex XI Part B will need to be repeated prior to launch of every device.

Q. Procedure Packs, Article 22. When you have more than one legal manufacturer in the kit and individually CE marked, is the outside of the box required to have a CE marking?

A. CE marking is not required on the outer box under Article 22.3 since all the devices within the pack already bear a CE mark.

Q. Can we sell a Class I (non-sterile, non-measuring) product with MDD declaration of conformity issued before 26 May 2020?

A. Class I devices cannot be placed on the market after 26 May 2020 based on a declaration of conformity that has been issued under the MDD.
Q. If a company is undergoing a name change but is still the same company – are separate applications needed? Or can you provide supporting evidence for all names in transition?

A. It is still slightly unclear on what happens under such circumstances for MDR certificates. Manufacturers are required to obtain an SRN when they originally register themselves on EUDAMED. It is unclear whether EUDAMED treats such name changes as a legal entity change and issue a new SRN or will allow the manufacturers to make administrative name changes without changing the SRN. Whether separate applications are required or not will depend on whether the underlying legal entity is changing due to the name change.

Q. What are the labelling expectations under MDR regarding compliance with ISO 15223 – are manufacturers expected to comply for all symbols or can we not claim compliance with ISO 15223 and move to using text alone?

A. ISO 15223 is not harmonized to the MDR but will be considered state of the art until it is harmonized. Symbols used that are not from ISO 15223 will need to be explained in the IFU.

Q. Under what circumstances would a company go for the type examination conformity assessment route?

A. Type examinations may be considered when there are product specific standards that describe the key functional characteristics of a type of device (e.g. Condoms, Gloves)

Q. By project plans for various devices, do you mean quality plans?

A. Manufacturers need to have established and documented plans (whether project plans or quality plans) that demonstrate clearly the timelines for conformity with the requirements of the MDR, associated responsibilities and the implementation phases/steps using which progress can be established during Notified Body audits.

Q. What type of conformity assessment would be required if a manufacturer has a Class III implantable custom-made device that utilizes a medicinal product ancillary to the custom-made device?

A. Custom-made Class III implantable devices will need to follow Annex XIII but will also need a Notified Body conformity assessment as per Chapter I of Annex IX or Part A of Annex XI. This applies even if the custom-made Class III implantable device consists of an ancillary medicinal substance. As per our current understanding, a medicinal consultation will not be required even though the custom-made device contains an ancillary medicinal substance since the consultation process is covered by Chapter II of Annex IX and not Chapter I. Please note that Annex XIII requires that the manufacturer issue a specific statement for custom-made devices and that this statement include an indication that the device contains or incorporates a medicinal substance if it does contain one.