General Safety and Performance Requirements (Annex I) in the New Medical Device Regulation

Comparison with the Essential Requirements of the Medical Device Directive and Active Implantable Device Directive

Laurel Macomber, Senior Manager, Medical Operations Shared Services, DePuy Synthes, and
Alexandra Schroeder, Product Expert, Vascular Devices Certification, BSI

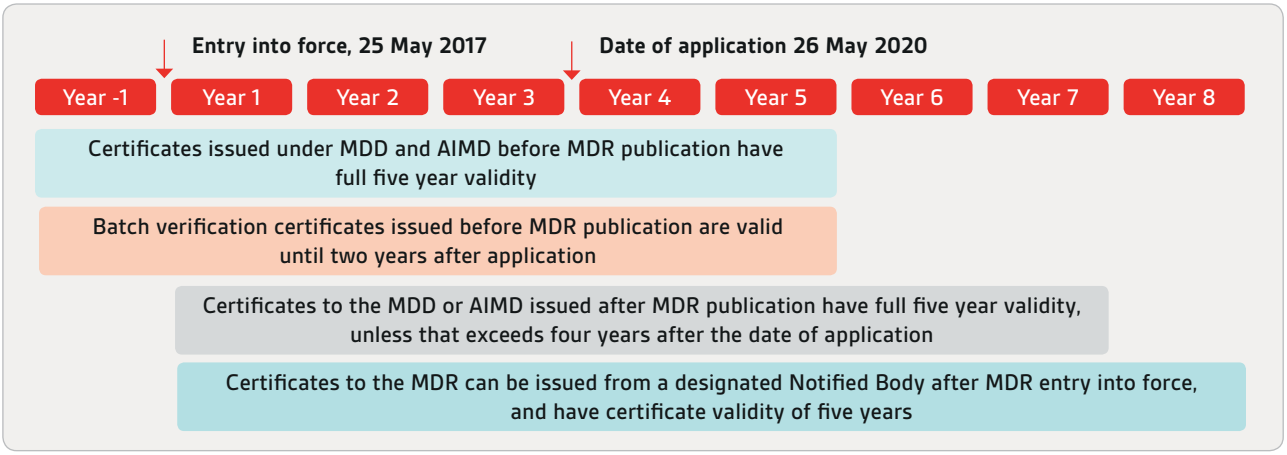
Contents

Introduction

As compliance with the 'Essential Requirements (ERs)' is the keystone for establishing conformity with the Medical Device Directive (MDD, 93/42/EEC) and Active Implantable Medical Device Directive (AIMDD, 90/385/EEC), so too is compliance with the 'General Safety and Performance Requirements (SPRs)' in establishing conformity with the recently published Medical Device Regulation – EU Regulation 2017/745 (MDR). The Regulation's date of publication was 5 May 2017 and date for Entry into Force was 25 May 2017 with a 3-year transition period. The purpose of this white paper is to compare the ERs in the MDD and AIMDD to the SPRs in Annex I of the new MDR. Where there are 13 ERs in the MDD and 16 in the AIMDD, there are 23 SPRs in the new MDR. The overall text and requirements are expanded, but the scope and topics are consistent overall with the previous directives with a few notable exceptions. Some topics such as clinical evaluation and medicinal consultation have moved from the requirements list into the articles, while other topics are new to the requirements list, including devices without a medical purpose and requirements for devices used by lay persons. A number of areas now have increased emphasis and more explicit requirements, which in many cases align with harmonized standards and industry guidances. Importantly, all of these points will now become European law under this Regulation. The areas in Annex I considered to have highest impact to manufacturers are:

- medicinal substances (and substances absorbed or locally dispersed);
- devices incorporating materials of biological origin;
- substances of concern;
- labelling requirements;
- emphasis on cybersecurity.

What is the plan for implementation of the MDR?



Note: *the blocks display the time period within which a certificate type can be valid, not the period of validity for a single certificate*

Other key areas of impact in the MDR outside Annex I include:

- clinical data and evaluation requirements;
- reclassification of some device types;
- post-market requirements.

These topics outside Annex I are beyond the scope of the current white paper, but manufacturers should be aware that these important areas are also changing in comparison to the directives. An updated white paper will follow focusing on the implications of the MDR and MEDDEV 2.7.1 Rev. 4 for clinical data and evaluation.

The paper is organized in order of the new safety and performance requirements by number, with the goal that the readers begin to become familiar with the new numbering and organization. The intent is not to reproduce each requirement, but to highlight areas of particular similarity and difference between the ERs and SPRs. While many of the SPRs (namely numbers 10-23) have explicit headings or titles, others have been added here in an attempt to highlight the theme of each requirement.

Cross-references to ERs and other documents with similar text have been identified for each requirement. In addition, each SPR has been graded (low, medium or high) relative to the expected impact of the changes to the manufacturer (see Appendix 1 for SPR/ER Cross-reference Mapping Guide).

Understanding the SPRs will be an important aspect of manufacturers' transition plans from the directives to the MDR.

SPR 1: Performance and safety

SPR 1 generally corresponds to AIMDD and MDD ER 1. In fact, much of the text is the same. This requirement states that the devices shall be 'designed and manufactured in such a way' that safety of patients and users shall not be compromised. As with ER 1 in the directives, this is under the normal conditions of use. The concept of 'performance' is brought in from AIMDD ER 2 and MDD ER 3 to this requirement. The design and construction should conform to safety principles, taking into account the 'generally acknowledged state of the art' as required in to MDD ER 2 and AIMDD ER 6. The risks related to ergonomic features and consideration of the use environment, present in MDD ER 1, have been moved to SPR 5.

SPR 2: Reduction of risks

SPRs 2-5 all relate to risk management. SPR 2 is a new, short and specific statement addressing the requirement to reduce risks as far as possible. It is clarified that this means reduction of risks as far as possible, without adversely affecting the risk-benefit ratio. This requirement is new versus the Directives, but is considered a clarification of the intent of the existing requirements in MDD ER 2 and AIMDD ER 8. In some cases, risks could be further reduced by changes in design, but important benefits and/or device performance may also be compromised by these changes, thus impacting the risk-benefit ratio. The risk reduction activities should not eliminate important device benefits without consideration of the risk-benefit ratio. The requirement to reduce risks as far as possible remain a discrepancy with the current risk management standard EN ISO 14971:2012, as addressed in Annexes ZA and ZB with respect to the Directives. This requirement continues to be to reduce risks as far as possible without regard for economic consideration.

SPR 3: Risk management system

SPR 3 is a new requirement without a general equivalent in the MDD and AIMDD. The basics of the risk management process are more explicitly defined in SPR 3, in alignment with EN ISO 14971:2012. While this is already an expectation of the harmonized standard which most manufacturers follow, this is now explicitly covered in the Regulation. It is noted that these points will now all be directly required as part of the risk management system, including evaluating of risks from foreseeable misuse.

SPR 4: Risk control measures and residual risks

SPR 4 generally corresponds to ER 2 in the existing MDD, and to a lesser extent, ER 6 in the AIMDD.

A new, more explicit requirement coming in from EN ISO 14971:2012 Annex ZA Point 4(c) is the requirement that both the overall residual risks *and* the residual risk associated with each hazard is evaluated and judged to be acceptable, with respect to the benefits. While this is already an expectation of the harmonized standard, this will now be explicitly included in the Regulation.

In addition, SPR 4 now more explicitly requires that warnings, precautions and contraindications be provided to users, in the context of residual risks. Whereas the MDD required users to be informed of the 'residual risks due to any shortcomings of the protection measures adopted,' the MDR says more broadly that the manufacturer 'shall inform users of any residual risks.' This SPR might be interpreted to mean that all residual risks including possible adverse events and side effects identified by the manufacturer in the risk management process should be disclosed in the information for users. This is further confirmed in SPR 23.4 with respect to the instructions for use (IFU) (discussed below).

SPR 5: Risks related to use

SPR 5 addresses reduction of risks relating to use error. This requirement generally corresponds to the latter part of ER 1 in the MDD. As already required by the MDD, the risk of use error shall be reduced as far as possible including ergonomic considerations and the knowledge, experience and types of users (e.g. clinicians, patients or caregivers). This is commonly known as usability or human factors. See BSI's earlier white paper–'*The growing role of human factors and usability engineering in medical devices*', which can be found here: http://www.bsigroup.com/en-GB/our-services/medical-device-services/BSI-Medical-Devices-Whitepapers/. While there is no clear AIMDD counterpart to this SPR, AIMDD manufacturers are likely already considering risks relating to use in the implantation process per harmonized standards. These requirements are now explicitly included in the MDR.

SPR 6: Device lifetime

SPR 6 defines requirements for the characteristics and device performance over the lifetime of the device as indicated. The 'device lifetime' requirement generally corresponds to ER 4 in the MDD and ER 3 in the AIMDD. Like the similar requirements in the Directives, SPR 6 requires that the device characteristics and performance shall not be adversely impacted to such a degree that health or safety of a patient or user would be compromised, when under the stresses of 'normal conditions of use.' The lifetime is defined here as the lifetime 'as indicated by the manufacturer,' which aligns with the MDD ER 4, and is a change from AIMDD ER 3 which referred to the lifetime 'anticipated by the manufacturer.'

Supplementing similar requirements of both Directives, this SPR now states that device performance must not be adversely impacted when the device 'has been properly maintained in accordance with the manufacturer's instructions.' Reasonably foreseeable maintenance or storage errors may be considered as part of use risk evaluation, but in some cases impacts to performance cannot be prevented when maintenance and storage are not per the manufacturer's instructions.

SPR 7: Packaging, transport, storage

Basic requirements for device packaging, transportation and storage are outlined in SPR 7. This requirement can be mapped to ER 5 in the MDD and ER 4 in the AIMDD. The intent of the requirement remains the same: that the device design, manufacturing and packaging will protect a device's characteristics and performance for intended use during transportation and storage, taking into account the [storage] instructions provided by the manufacturer. The requirement specifically gives the example of potential temperature and humidity fluctuations (as in AIMDD ER 4), which are already typically considered by manufacturers in transportation simulations and storage restrictions on device labelling if necessary.

SPR 8: Risk-benefit ratio

The MDR includes an updated definition of the 'risk-benefit ratio' to be assessed by the manufacturer in SPR 8. This risk-benefit evaluation per MDD ER 6 and AIMDD ER 5 corresponds to new SPR 8. It now includes 'all known and foreseeable risks,' and that the risks 'shall be minimized.' The risks are explicitly weighed against the 'evaluated benefits to the patient and/or user arising from the achieved performance,' rather than the 'performances intended.' Lastly, the risk-benefit evaluation is clarified to be 'during normal conditions of use.' This might be interpreted as per the intended use and reasonably expected conditions of use. The intent of the risk-benefit evaluation remains the same, and the requirement itself is not new compared to the two Directives.

SPR 9: Devices without a medical purpose

Devices without a medical purpose are excluded from the scope of the MDD and AIMDD, but are included in the MDR. SPR 9 clarifies how to apply the 'risk-benefit' and 'performance' requirements (SPRs 1 and 8) for those devices without a medical purpose or medical benefit. It is stated that the devices 'shall not present any risk' or 'no more than the maximum acceptable risks' consistent with a high level of protection for safety and health. Devices without a medical purpose also have specific labelling/IFU requirements (see SPR 23.4 (x)). Annex XVI of the Regulation is devoted to a listing of these devices, and per Article 1.2 of the Regulation, Common Specifications (CS) are planned to be adopted to address these devices with respect to risk management and clinical evaluation of safety. It is anticipated that the CS specific to various device types (as provided for in MDR Recital 23 and 24) will add clarity to the expectations for the 'maximum acceptable risks' and acceptably high levels of safety. However, in the absence of CS, manufacturers must justify what the 'maximum acceptable risks' are. Such justifications would likely include reference to industry guidances or standards for those devices or for similar devices with a medical purpose, to establish a comparison to the accepted state of the art. Although SPR 9 is specific to the devices with no medical purpose, interpretation of the Regulation expects that these devices will comply with all of the safety and performance requirements in Annex I, with only the special allowances here for SPRs 1 and SPR 8.

Common specifications

The Medical Devices Regulation has provided for 'CS' in Article 9. These are defined in Article 2 as a set of technical and/or clinical requirements other than standard that provide a means of complying with the legal obligations applicable to a device, process or system.

Article 9 states that CS will be adopted where no harmonized standards exist–OR–where relevant harmonized standards are not sufficient–OR–where there is a need to address public health concerns. These CS will be developed by expert panels appointed by the Commission, in consultation with the Medical Device Coordination Group (MDCG, Article 103)

Devices in conformity with CS shall be presumed to be in conformity with the relevant requirements of the MDR. The MDR states that manufacturers shall comply with applicable CS unless they can duly justify that their solutions ensure at least an equivalent level of safety and performance. Finally, manufacturers of the devices without a medical purpose as listed in Annex XVI are required to comply with any relevant CS for those products.

Manufacturers should monitor the Commission website for developments. CS are likely to be published in the Official Journal of the European Union, as is currently done for the similar in vitro diagnostic 'Common Technical Specifications.'

The specific requirements in the text of SPR 9 are primarily a clarification on the application of other requirements in the list (SPRs 1 and 8). However, it is noted here that the inclusion of devices without a medical purpose under the scope of the MDR brings with it potentially significant work for manufacturers whose devices did not previously overlap with medical use indications to meet the extensive requirements of this new Regulation.

SPR 10: Chemical, physical and biological properties

The text and requirements of SPR 10 are generally similar to subparts of MDD ER 7, and AIMDD ER 9, broadly regarding biological safety. The text of SPR 10 is somewhat expanded in comparison to the corresponding requirements in the MDD or AIMDD. The text is greatly expanded in the areas of specific substances of concern (SPR 10.4).

SPR 10.1: General considerations for materials

SPR 10.1 generally corresponds to ER 7.1 in the MDD and ER 9 in the AIMDD. This SPR outlines basic considerations for materials with respect to the device function as well as toxicity and biological safety.

SPR 10.1 (b) is similar to requirements in both Directives that materials should be compatible with the body tissues, cells and fluids considering the intended purpose. However, 'substances' used are specifically included in this consideration, as are the body's processes: '[taking into account] where relevant, absorption, distribution, metabolism and excretion.'Many of the listed considerations are material properties already considered as part of a typical design process. For example, SPR 10.1 (c) states that consideration should be given to compatibility between different parts of a device. This is something which manufacturers would almost certainly be considering already with respect to function as well as biological safety; however, the requirement is now specifically included as a design consideration. Robust product development and biological safety programs will already be considering the impact of manufacturing processes on the device function and biological safety, but SPR 10.1 (d) now includes this as a specific requirement. SPR 10.1 (f), (g) and (h) are all new in comparison to the Directives. These aspects of materials are likely already considered as part of the design process. SPR 10.1 (h) seems to point to the importance of physical and chemical characterization as part of the design process and biological safety evaluation.

SPR 10.2: Risks from contaminants and residues

SPR 10.2 generally corresponds to ER 7.2 in the MDD, and does not have a clear counterpart in the AIMDD. The requirement is largely unchanged from MDD ER 7.2 other than a rearrangement of words.

SPR 10.3: Compatibility with materials and substances

SPR 10.3 generally corresponds to ER 7.3 in the MDD and does not have a clear counterpart in the AIMDD. The requirement is largely unchanged in comparison to MDD ER 7.3 aside from detail around devices administering medicinal products. This requirement adds text regarding performance [in accordance with their] 'respective indications.' This change could be interpreted as clarifying the medicine delivered by the medical device is to be used within its approved indications, excluding 'off-label' use. Aside from the noted clarification on medicinal substances, SPR 10.3 is considered highly similar to MDD ER 7.2. Although there is not a clear counterpart in the AIMDD, the considerations of compatibility are likely already being addressed as part of other requirements for these devices under the AIMDD.

SPR 10.4: Substances contained in and released from the device

Special attention in our discussion is given to the subrequirements in SPR 10.4 regarding 'Substances,' which focuses most on substances of particular concern. The text of 10.4 is much longer than any corresponding requirement in the two Directives, and was added in a later draft of the proposed Regulation. The requirements regarding these substances are also much more specific than any previous requirement in the two Directives.

The most significant new text is the requirement for certain substances of concern that invasive devices or devices administering/storing substances must contain a concentration below 0.1 per cent by weight (stated in SPR 10.4.1) unless justified with reference to SPR 10.4.2. This includes carcinogenic, mutagenic, or toxic to reproduction (in total referred to as 'CMR') substances and substances with endocrine-disrupting properties. The SPR makes reference to substances categorized per EU Regulation 1272/2008 (Classification, Labelling and Packaging of Chemicals) and substances identified in EU Regulation 1907/2006 (REACH: Registration, Evaluation, Authorisation, and Restriction of Chemicals) or EU Regulation 528/2012 (Market and Use of Biocidal Products).

A justification as per SPR 10.4.2 must be made if the CMR or endocrine-disrupting substances (for example: lead compounds, other heavy metals, phenols) are present above 0.1 per cent by weight in these device types. This subsection 10.4.2 lists the aspects to be included in the justification for inclusion of these substances.

SPRs 10.4.3 and 10.4.4 state that the European Commission shall provide the scientific committee provided for in the Regulation with a mandate to prepare guidelines including a risk-benefit assessment of phthalates as well as other CMR and endocrine-disrupting substances. Phthalates are currently addressed in MDD ER 7.5 and not specifically

addressed in the AIMDD. There is no immediate action required for manufacturers at present; however, manufacturers of devices including phthalates, CMR substances, or endocrine-disrupting substances must keep these forthcoming guideline reports in mind and account for this in plans to meet the MDR requirements. Manufacturers may reference as examples similar opinion reports from the scientific committee on emerging and newly identified health risks (SCENIHR).

SPR 10.4.5 addresses labelling requirements for devices which include substances as referred to previously, in concentrations above 0.1 per cent by weight. This information must be disclosed on the label, and specific information on treatment of vulnerable groups including children and pregnant and breastfeeding women must be included in the IFU. This section is cross-referenced from the labelling requirement, SPR 23.2(f).

The text and requirements for substances in the device, and especially substances of toxicological concern, are greatly expanded in the MDR. A threshold and reference for substances of concern are now specifically defined, and considerations for justification are outlined if these substances are included in a medical device. Manufacturers should be aware of what substances are present in their devices. The specific requirements will further increase the need for careful characterization of device substances and materials going forward.

SPR 10.5: Risk of unintentional ingress

SPR 10.5 corresponds directly to ER 7.6 in the MDD. The risk of unintentional ingress is to be reduced as far as possible. The sixth bullet of AIMDD ER 9 regarding devices being 'leakproof' roughly corresponds to SPR 10.5.

SPR 10.6: Risks related to particle size

SPR 10.6 is a new requirement compared with the Directives. This states that risks linked to the size and properties of particles should be reduced as far as possible, unless these come into contact with intact skin. It is stated that 'special attention shall be given to nanomaterials.' The consideration of nanomaterials is a new more contemporary requirement. Under the classification Rule 19 in MDR Annex VIII, the risk class of devices incorporating a nanomaterial is dependent on the level of potential for internal exposure. The new emphasis on nanomaterials will be very important for many devices for which this may not have been a major concern under the Directives.

SPR 11: Infection and microbial contamination

The text and requirements of SPR 11 are generally similar to subparts of MDD ER 8, and to a lesser extent AIMDD ER 7, regarding infection and microbial contamination.

SPR 11.1: Risk of infection

SPR 11.1 generally corresponds to MDD ER 8.1, but SPR 11.1 contains more specific examples. This requirement does not have a specific counterpart in the AIMDD, although the AIMDD includes requirements for sterility in ER 7.

SPR 11.1 (a) is a requirement not found in either Directive and was added in a later draft of the proposed Regulation. This requires that the design shall reduce the risks from unintended cuts and pricks (such as needle sticks) as far as possible 'and appropriate.' Numerous National Institute for Health and Care Excellence (NICE) and industry guidance documents are available on reduction of needle and sharps injuries, particularly with respect to usage factors.

SPR 11.1 (b) requires easy and safe handling and is aligned with MDD ER 8.1.

SPR 11.1 (c) of this requirement relates to reducing microbial leakage or exposure from the device. This may be interpreted as related to devices such as devices for sample collection, and anticipate that this is a clarification on a risk reduction already expected but now more clearly defined.

SPR 11.1 (d) may relate to devices such as reusable devices or those for collection of specimens and samples. Based on the device function, this requirement may be already expected by your notified body, but is now more explicitly defined.

The general intent of SPR 11.1 corresponds to MDD ER 8.1, with additional specificity, particularly for specimen and sample collection devices.

SPR 11.2: Design for reuse

SPR 11.2 represents a new requirement without a counterpart in either of the Directives. The requirement that devices be designed to facilitate safe cleaning, disinfection and/or resterilization has always been applied to devices designed to be reusable, such as surgical instruments. It is not entirely clear whether this requirement is intended to also apply to single use devices which are reprocessed by the manufacturer or a third party. This requirement may be interpreted as not applicable to those devices intended by the original manufacturer to be for single use, but primarily applicable to devices specifically designed for reuse, given the words 'where necessary' in the text.

SPR 11.3: Devices with a specific microbial state

SPR 11.3 is new requirement for devices with a 'specific microbial state.' This may be interpreted as a clarification, given that some devices (such as filter-sterilized liquids) have a different sterility assurance level. This requirement is considered to clarify that the microbial state should be defined and properly validated.

SPR 11.4: Devices delivered sterile

SPR 11.4 corresponds to MDD ER 8.3 and AIMDD ER 7, relating to design and manufacturer of devices provided sterile. The language has been updated compared with the text in the Directives. The 'non-reusable pack' language has been removed, and the storage and transport conditions are clarified as those 'indicated by the manufacturer.' The last sentence states, 'These measures shall ensure that the integrity of the sterile packaging is clearly evident to the final user.' This may be interpreted as a clarification of the requirement to ensure integrity through the product life cycle including handling, storage and delivery. Manufacturers must consider the clarity of packaging integrity to prevent the use of breached packaging which may mistakenly be thought to be intact.

SPR 11.5: Validation for sterile devices

Like corresponding MDD ER 8.4, SPR 11.5 requires that sterile devices are manufactured and sterilized by an appropriate, validated method. The MDR has changed 'devices delivered in a sterile state' to 'devices labelled as sterile,' which better reflects the capability of a manufacturer; handling and storage cannot be controlled to ensure delivery in a sterile state. The end user of sterile device still needs to inspect and determine acceptability of the packaging, as alluded to in SPR 11.4. Additionally, the requirement now includes that devices labelled as sterile shall be 'packaged' by appropriate validated methods. The validation of processes for sterile barrier systems is a provision of ISO 13485:2016 (Clause 7.5.7), which also refers to harmonized standards ISO 11607-1 and ISO 11607-2 which cover packaging requirements and packaging validation for terminally sterilized medical devices. The requirement for packaging system validation is not considered new for manufacturers, but is now specifically included in the MDR's safety and performance requirements.

SPR 11.6: Environmental controls

SPR 11.6 corresponds very closely to MDD ER 8.5, and does not have a like-for-like counterpart in the AIMDD. Minor changes to the wording have been made from the MDD, the most significant of which is including 'packaging' along with manufacturing in appropriately controlled facilities. This is considered to close a gap that may have existed for uncontrolled packaging areas. This is expected to be a clarification in line with existing practices, now explicitly required.

SPR 11.7: Packaging for non-sterile devices

SPR 11.7 corresponds to MDD ER 8.6 and has no counterpart in the AIMDD because such devices are always provided sterile. The wording of SPR 11.7 is nearly identical to MDD ER 8.6, but now states that the packaging shall maintain the 'integrity and cleanliness' rather than keeping the product 'without deterioration at the level of cleanliness stipulated.' Similar to the requirements in ISO 13485:2016 Section 7.5.2, the requirement as written clarifies that cleanliness is required for non-sterile devices, and closes gaps for aspects such as particulate matter on non-sterile product.

SPR 11.8: Labelling for sterile state

SPR 11.8 can be traced to MDD ER 8.7 and has no counterpart in the AIMDD because such devices are always provided sterile. While the requirement is highly similar, the MDR has added wording that the label distinguishing between sterile and non-sterile conditions is 'additional to the symbol used to indicate that a product is sterile.' Harmonized symbols exist to indicate sterility as well as non-sterile product, but it is not clear what other labelling would be expected to demonstrate compliance with this requirement. See section on SPR 23.1 (h) below for further discussion of harmonized symbols.

SPR 12: Devices incorporating a medicinal product; substances absorbed or locally dispersed

SPR 12 deals with the requirements for medicinal products or substances which are absorbed or locally dispersed in the body. Medicinal substances were previously addressed in MDD ER 7.4 and AIMDD ER 10; however, the scope of SPR 12 has significantly changed in comparison to the Directives.

Perhaps the most significant change in comparison to the Directives is that the definition of what is included along with the medicinal considerations now includes 'substances or combinations of substances that are absorbed by or locally dispersed in the human body.' The addition of devices including these substances gives a broader scope than ER 7.4.

SPR 12.1: Devices incorporating a medicinal product

As with the current medical devices Directives, Directive 2001/83/EC (covering medicinal products for human use) is referenced for the definition of medicinal products. However, the qualification of 'liable to act upon the body with action ancillary to that of the device' is gone. SPR 12.1 refers back to Article 1(8) of the Regulation, which determines what combination products are in scope of this Regulation; the provision for the medicinal substance having an action 'ancillary to that of the device' is present here. In this sense, the determination of a product as a medicine versus a device by its primary and ancillary action has not changed. However, the phrase 'liable to act' has been removed entirely from the Regulation in comparison to the Directives. The full implications of this are currently unclear, but it is noted that reference to the 'ancillary action' remains in the Article 1(8) definition and Rule 14. Ultimately, the applicability of Rule 14 and SPR 12.1 will lead to the competent authority consultation process.

The particulars of competent authority consultation are not included in the SPRs, unlike the Directives. The procedure is now outlined in Annex IX, Chapter II, Section 5.2 of the Regulation.

SPR 12 would remain applicable to medicinal products derived from human blood or human plasma; however, aspects specific to human-derived substances are now detailed in a separate requirement, SPR 13.1.

SPR 12.2: Devices composed of substances absorbed or locally dispersed

SPR 12.2 includes entirely new specific provisions for devices composed of substances which are introduced into the body and absorbed or locally dispersed in the body. This requirement states that such devices should comply with the

relevant requirements in Directive 2001/83/EC for medicinal products for 'the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions' per the applicable conformity assessment procedure undertaken per MDR. As with the existing ERs and Classification Rules, it will be up to a manufacturer to determine what SPRs and rules apply to their device including these for absorbed and dispersed substances.

The requirement for absorbed substances is not limited to biocompatibility but now includes a larger scope. The aspects as listed will have to be demonstrated by manufacturers and verified by the notified bodies. The need for competent authority consultation for such devices is defined in Annex IX, Chapter II, Section 5.4 of the Regulation if the devices or their metabolic products are absorbed in order to achieve their intended purpose.

SPR 13: Devices incorporating materials of biological origin

The topic of materials of biological origin is an area of high impact and change in the MDR safety and performance requirements, expanding upon the scope of the MDD. The requirements in SPR 13 generally correspond to MDD ERs 7.4 and 8.2; the AIMDD did not have explicit requirements in its text for animal or biological tissues incorporated into devices, but human blood derivatives were previously covered in AIMDD ER 10.

SPR 13.1: Tissues, cells or derivatives of human origin

Although human blood derivatives were previously within scope of MDD ER 7.4 and AIMDD ER 10, the MDR now includes requirements for devices utilizing non-viable tissues or cells of human origin, or their derivatives. This category has expanded the scope of the Regulation, as these were specifically excluded from the MDD (Article 1, 5(f)) with the exception of medicinal products derived from human blood or plasma. The MDR now includes devices incorporating non-viable human tissues or cells in scope, and SPR 13.1 defines the requirements for these, with a focus on safety and traceability in the context of existing Directives.

SPR 13.2: Tissues, cells or derivatives of animal origin

The requirements in SPR 13.2 generally correspond to MDD ER 8.2. The MDR references existing EU Regulation 722/2012 for tissues of animal origin. The expanded text in SPR 13.2 may be interpreted as generally consistent with the requirements of EN ISO 22442-2 and Regulation 722/2012 (both concerning requirements for utilizing tissues of animal origin in medical devices). Although the text is expanded when compared to the MDD ERs, the consistency with the animal tissue standard and Regulation should mean that the impacts on manufacturers are low in the area of tissues, cells and derivatives of animal origin.

SPR 13.3: Other non-viable biological substances

The requirements of SPR 13.3 relate to a new category of consideration, not discussed in the MDD: 'other non-viable biological substances.' As with the other categories of biologically derived materials, the focus is on safety for patients and users, with particular attention to viruses and transmissible agents. This 'catch-all' category would include any non-viable biological substances derived from or produced by a living organism, other than the more specific human and animal categories previously outlined. This could include recombinant proteins produced by bacteria, for example. Some of these substances may also be medicinal products, in which case SPR 12.1 would also apply.

SPR 14: Construction of devices and interaction with their environment

SPR 14 corresponds to ER 9 in the MDD, along with ER 10.2 for ergonomic principles. This SPR corresponds less specifically to content in AIMDD ERs 8 and 9 relating to the environment and device compatibility. The additions

and changes in SPR 14 in comparison with the MDD and AIMDD may already be addressed as part of compliance with standards in some cases, and in other cases, more specific considerations will need to be made to address the aspects of SPR 14.

SPR 14.1: Use in combination

SPR 14.1 corresponds to ER 9.1 in the MDD, with new text added in the last sentence. The new text states, 'Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimize all possible risks, such as misconnection.' This may be interpreted as not a truly new requirement, but certainly the MDR is more explicit and emphasized in this subject. Requirements of the Directives already specified safe connections, and harmonized standards (i.e. EN 60601-2-24 (requirements for infusion pumps and controllers), EN ISO 18082:2014 (requirements for medical gas connectors)) also address connections with patient gas and fluid lines, among other things. SPR 14.1 aligns with the more recent standards emphasis on non-compatible connector standards (ISO 80369 series) to prevent misconnections. This point is considered to bring more emphasis and clarity in this area but not a truly new requirement. SPR 14.1 is otherwise nearly identical to MDD ER 9.1. SPR 14.1 also corresponds to the fourth bullet of AIMDD ER 9, specifying safe connections, but with additional detail.

SPR 14.2: Risks of interaction with the environment

Much of SPR 14.2 (a, b, f and g) is traceable to MDD ER 9.2. SPR 14.2 (c) relates to MDD ER 7.3, and SPR 14.2 (e) is again similar to ER 7.6. SPR 14.2 (d) is new in comparison to the MDD.

SPR 14.2 includes the content of the first, third and last bullet of AIMDD ER 8 in requirements for construction of devices and interaction with their environment. Other portions of SPR 14.2 have no corresponding AIMDD ER.

SPR 14.2 (b) adds consideration of 'radiation associated with diagnostic or therapeutic procedures,' 'humidity,' and 'radio signal interferences' to the list of specific risks to be removed or reduced as far as possible. This may be interpreted as more explicit detail on what was previously expected. Electromedical products already consider environmental conditions including humidity and interference per EN 60601-1. Devices emitting radiation are already designed so as to reduce this risk as far as possible in line with current requirements of the MDD and AIMDD.

SPR 14.2 (d) is considered a more significant change in the Regulation versus the Directives because it is explicitly addressing risks for software at the system and network level. This includes consideration of the final system configuration during software/product validation, consideration of cybersecurity and network potential risks and information to the user for IT networks that cannot be validated by the manufacturer. These issues are currently somewhat addressed in EN 60601-1 (requirements for medical electrical equipment) and IEC/ISO 80001 series (risk management for IT networks incorporating medical devices) and IEC 82304-1 (health software), but cybersecurity and network considerations have not been specifically mentioned in either of the Directives. Your notified body may be considering this already in medical device applications, and SPR 14.2 will make this more explicit in the future that manufacturers and notified bodies must address this risk. This risk of possible interaction between software and the IT environment should be specifically considered in risk management documentation to demonstrate compliance with this requirement.

SPR 14.3: Risks of fire or explosion

SPR 14.3 directly corresponds with ER 9.3 in the MDD, with a few words of clarification. The intent of the requirement appears to be the same as in the MDD. There is no direct counterpart in the AIMDD.

SPR 14.4: Design for adjustment, calibration and maintenance

SPR 14.4 is a new requirement in comparison to both Directives, that devices be designed and manufactured for safe and effective adjustment, calibration and maintenance. While the ERs have covered risks where calibration and

maintenance are impossible or providing information for maintenance, this is a new specific requirement. This may already be addressed by manufacturers as part of usability.

SPR 14.5: Design for compatibility

SPR 14.5 is similar to SPR 14.1, corresponding to MDD ER 9.1, but in addition to safe connections and compatibility, this SPR mentions 'reliable' interoperability and compatibility for devices intended for use with other devices or products.

SPR 14.6: Measurement, monitoring or display scales

SPR 14.6 can be correlated to MDD ER 10.2 but elaborates on taking account of the 'intended purpose,' including also the intended users and intended environmental conditions of use with respect to ergonomics of the measurement, monitoring or display scales. There is no direct counterpart in the AIMDD.

SPR 14.7: Design and manufacture for safe disposal

SPR 14.7 is a new requirement not found in either of the Directives. While the directives required the IFU to include warnings about safe disposal (see MDD ER 13.6 (n) AIMDD ER 15 Part 14), SPR 14.7 requires that devices are specifically designed and manufactured to facilitate their safe disposal, and the safe disposal of any related waste substances by the user, patient, or other person. Manufacturers are required to actually identify and test procedures and measures for disposal of their devices and describe these procedures in the IFU (see SPR 23.4 (v)).

SPR 15: Devices with a diagnostic or measuring function

SPR 15 generally corresponds to ER 10.1 and 10.3 in the MDD and does not have a direct correlation in the ERs of the AIMDD. In comparison to the MDD, 'diagnostic devices' have been added to the scope of the requirement. The consideration of 'precision' has been added. Measurements from measuring devices are still required to be expressed in legal units per Directive 80/181/EEC. The intent of the requirement remains the same as in the MDD.

SPR 16: Protection against radiation

The requirements for protection against radiation in SPR 16 generally correspond to parts of ER 11 in the MDD. SPR 16.4 regarding ionizing radiation also corresponds to a portion of ER 8 in the AIMDD; the other requirements for radiation are not included in the AIMDD.

SPRs 16.1 (a) and 16.2 (b), 'General' requirements correspond to MDD ERs 11.1 and 11.4, respectively. The only new aspect is the requirement that 'Information regarding the acceptance testing, the performance testing and the acceptance criteria, the maintenance procedure shall also be specified [in the operating instructions for devices emitting hazardous or potentially hazardous radiation.]' This will affect operating manuals for such devices if this information is not already included.

SPRs 16.2 (a) and 16.2 (b) 'Intended radiation' requirements correspond to MDD ERs 11.2.1 and 11.2.2, respectively, with only slight rewording.

SPR 16.3 for 'Unintended radiation' corresponds to MDD ER 11.3, but with the addition of the last sentence: 'Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected.' While this is likely already considered in design and driven by risk management, evidence of compliance will now be required for this SPR.

SPR 16.4 'Ionizing radiation' can be related to MDD ERs 11.5 and 8, with some changes. SPR 16.4 (a), (c) and (d) can be mapped to MDD ERs 11.5.1, 11.5.2 and 11.5.3, respectively, while SPR 16.4 (b) is a new requirement. The reference to Directive 2013/59/Euratom (safety standards for protection against ionizing radiation) in SPR 16.4(a) updates the superseded references to 96/29/Euratom and 97/43/Euratom (superseded Directives on the same subject) in the AIMDD; these Directives were not previously referenced in the MDD. Reference to this Directive for all device manufacturers will have some implications. The main impact on manufacturers may be the need to implement control measures for radiation protection in the manufacturing process, and implement a means of measuring effective absorbed doses over the year. This includes personal monitors as well as radiation leakage surveys. It is anticipated that these measures are generally implemented by manufacturers of radiotherapy devices, but we note that this now becomes mandatory as the 2013/59/Euratom Directive is directly referenced by the MDR safety and performance requirements. It is also noted that SPR 16.4 (b) contains text not found in either of the MDDs. This point requires that device emitting ionizing radiation should ensure that the quantity, geometry and quality of the emitted radiation can be varied, controlled and monitored if possible, taking into account the intended use.

SPR 17: Electronic programmable systems and software

SPR 17 defines requirements for electronic programmable systems and software considered to be a medical device in itself.

SPR 17.1 generally corresponds to ER 12.1 (first sentence) in the MDD, and SPR 17.2 generally corresponds to MDD ER 12.1a and AIMDD ER 9 (last indent). The wording in the Regulation now includes 'software that are devices in themselves' more explicitly in the scope of these requirements. In addition, principles of 'information security' are new in comparison to MDD ER 12.2 and AIMDD ER 9. Cyber security is a new area of emphasis in the MDR when compared to the Directives, as seen across multiple safety and performance requirements.

SPR 17.3 defines specific requirements for software to be used with mobile computing platforms. This contemporary consideration is certainly new when compared to the older Directives. Manufacturers are asked to consider the specific features of mobile platforms, including screen size and limitations, and light and noise in the use environment. Manufacturers may undertake usability testing as well as validation testing, among other things, to address compliance with SPR 17.3.

SPR 17.4 is new when compared to the MDD and AIMDD; however, detailed hardware and minimum requirements are already addressed in EN 60601-1+A1 (requirements for medical electrical equipment), and so it is expected that most manufacturers of these devices already meet this requirement. The requirement is brought directly into the Regulation with this item and as such, the manufacturer's documentation must reference these points directly. SPR 17.4 also adds additional detail, again addressing cyber security and data protection. Manufacturers should consider these aspects including data encryption, levels of access and username/password formats. BSI has published an earlier white paper on cybersecurity, which can be found here: http://www.bsigroup.com/en-GB/our-services/medical-device-services/BSI-Medical-Devices-Whitepapers/

SPR 18: Active devices and devices connected to them

SPR 18 defines particular requirements for active devices. A majority of this requirement corresponds to subparts of ER 12 in the MDD.

SPR 18.1 generally corresponds with MDD ER 12.1 (second sentence) with the clarification now for 'non-implantable active devices.'

SPR 18.2 corresponds in part to ER 12.2, with the addition of a warning or indication for low power supply. The concept of a 'low battery indicator' for these devices is already an expectation per EN 60601-1-11 and 60601-1-12, but is now more explicitly required by the MDR.

SPRs 18.3 and 18.4 are essentially identical to MDD ERs 12.3 and 12.4.

SPR 18.5 generally corresponds to MDD ER 12.5. The instruction to reduce risks of creating 'electromagnetic fields' has been clarified to 'electromagnetic interference' and the interference that could impair 'other devices' is clarified to 'this or other devices.' This SPR may be considered a clarification of present practice for EN 60601-1-2 (EMC standard), and is still covered by EMC emissions testing.

SPR 18.6 includes new text not found in the two Directives. It is required to design and manufacture devices for intrinsic immunity to electromagnetic disturbance. This SPR may also be considered a clarification on current practice for EN 60601-1 and EN 60601-1-2 (EMC standard) and risk management. It is also noted that the wording of this requirement leads to the idea of good EMC emissions and immunity by design, rather than correction of problems after a device has failed testing.

SPR 18.7 corresponds to MDD ER 12.6 with minor wording changes, and aligns with the requirements in EN 60601-1.

SPR 18.8 is new text not found in the MDD or AIMDD. This requirement relates to cybersecurity as emphasized in SPR 17. This could include protections such as key switch locks or codes preventing unauthorized use. As with SPR 17, this requirement adds emphasis and attention to security and levels of access.

SPR 19: Particular requirements for active implantable devices

SPR 19 defines particular requirements for active implantable devices. The requirements can be generally mapped to ERs in the current AIMDD. With the merging of the MDD and AIMDD requirements into the single MDR, many of the adjacent requirements for active implantable devices have moved and are listed under the respective SPRs.

SPR 19.1: Particular risks to be reduced for active implantable devices

SPR 19.1 corresponds to previous ER 8 in the AIMDD. Parts (a), (b) and (c) of this SPR correspond to the second, fourth and sixth bullet of AIMDD ER 8, respectively. The other requirements captured in ER 8 have not been removed, but are now represented in other SPRs as part of the merging of the two Directives (see SPR 14.2, SPR 16.4). No major changes or additions have been noted in SPR 19.1 in comparison to the current requirements in the AIMDD ERs.

SPR 19.2: Device compatibility and reliability of energy

SPR 19.2 corresponds to ER 9 in the AIMDD. The two bullets correspond to the third and fifth bullet of AIMDD ER 9. The other requirements currently captured in ER 9 have not been removed, but now are represented in other SPRs as the two Directives have merged into the Regulation (see SPRs 10.1, 14.1, 17).

SPR 19.3: Identification of devices and components

SPR 19.3 includes the requirement to identify active implantable devices and their components to allow follow-up actions on any potential risks associated with the device or components. AIMDD manufacturers will recognize this requirement as AIMDD ER 11, and other than minor wording changes, this requirement has not changed. The intent is considered to be the same, and the expectations for AIMDD manufacturers are unchanged for this requirement.

SPR 19.4: Identification code

SPR 19.4 will be familiar to manufacturers of active implantable devices AIMDD ER 12. Previous drafts of the Regulation qualified the identification code for the device and manufacturer as 'Basic UDI-DI/SRN.' While this has been removed from the final draft of the text, the Unique device identification (UDI) expectations outlined in the MDR (Annex VI Part C) will apply to all devices including active implantable devices, and it is possible that AIMD

manufacturers will now meet the requirements for device identification using the Basic (device model) UDI-DI. Similarly, although SPR 19.4 does not explicitly require that the manufacturer be identified by its 'Single Registration Number' or SRN as defined in Article 31, it is possible that manufacturers may use the SRN to meet the relevant requirement of SPR 19.4.

SPR 20: Protection against mechanical and thermal risks

The requirements in SPR 20 can be directly correlated to ER 12.7 in the MDD. SPR 20 has no direct correlation in the AIMDD.

SPR 20 is nearly identical, part by part, to MDD ER 12.7 with the exception of subpart 20.5, which is new text not found in the MDD. This new requirement relates to errors that could be made in fitting or refitting parts. Manufacturers are likely already expected by their notified bodies to address these risks in alignment with current standards and as part of usability, but these considerations are now more explicitly stated in SPR 20.5 and should now be specifically addressed by manufacturers and notified bodies.

Although SPR 20 does not have an analogue in the AIMDD, protection against mechanical and thermal risks are already expected to be addressed in risk management and testing in the active implantable standards series EN ISO 14708 and EN 45502. SPR 20 will more explicitly state the requirements for consideration of these risks for AIMD manufacturers in comparison with the current Directive.

SPR 21: Protection against the risks posed to the patient or user by devices supplying energy or substances

SPR 21 corresponds to ERs 12.8.1, 12.8.2 and 12.9 in the MDD, and to a lesser extent, ER 9 in the AIMDD. The changes in comparison to the MDD are limited to minor rewording of the requirement; the intent is unchanged. The text of this requirement is new in comparison to the AIMDD. However, it is expected that consideration of the risks from supplied energy are already being comprehensively considered by manufacturers of active implantable devices where applicable. The requirements in SPR 21 are considered to be a very low impact item for MDD manufacturers and a relatively low-impact item for AIMDD manufacturers.

SPR 22: Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

Specific requirements for devices used by lay persons are new in the Regulation, and in fact the use of the 'lay person' term is new compared to both MDDs. For devices with lay persons as end users, SPR 22 outlines requirements and considerations for the device's instructions, variation in user technique, risks of error and injury, and verification of device function by the user. Devices for use for lay persons also have specific requirements for labelling and instruction for use which are included in SPR 23 (below).

SPR 22 as a whole likely aligns with what is already expected from manufacturers of such devices, but now provides a more explicit reference. For example, notified bodies likely already expect to see documentation of user needs and verification and validation with respect to the intended lay person users. Although the concept is not found in the text of the Directives, it is anticipated that this is overall a low impact item for manufacturers of devices used by lay persons as standards such as EN 60601-1-11 and EN 62366 consider these issues.

SPR 23: Label and instructions for use

SPR 23 deals with product labels and IFU. The text and requirements for labels and IFUs are greatly expanded compared with both Directives (MDD ER 13 and AIMDD ERs 14-15). An entire 'chapter' of the three chapters for safety and performance requirements is dedicated to SPR 23.

SPR 23.1: General requirements for information supplied by the manufacturer

SPR outlines general requirements for labels as well as the IFU.

A new requirement found in the first paragraph of SPR 23.1 (added in a later draft of the Regulation) states that the general information needed to identify the device and its manufacturer, and communicate safety and performance related information to the users should be made available on manufacturer's website (if applicable) and kept up to date. This would be in addition to the required labelling and IFU accompanying the device. The information to be provided on the website is described generally here but may include the IFU or sample labels. We note that provision of electronic IFU in addition to paper IFU is permitted for all devices per Regulation 207/2012 (requirements for electronic IFU of medical devices), but that certain requirements of that Regulation must still be met for the electronic IFU (eIFU) system. If IFUs are provided on manufacturer's website to meet this requirement of SPR 23.1, it seems likely that manufacturers will also need to address the relevant provisions of Regulation 207/2012 Article 9, for consistent content, website hardware and software protections, protection of personal data, and version control and availability. It also is notable that this paragraph requires performance related information to be communicated to the user. While MDD ER 13.6 (b) requires the intended performance of the device to be included, it does not require information on clinical benefits or any clinical summary. Further information regarding this is found in IFU requirements SPR 23.4 (c), (d) and (e).

SPR 23.1 (a) requires that the label and IFU should be clear in format, medium, legibility, content, etc., with respect to the intended users and their expected knowledge and experience. The focus of this requirement is on clarity and on the intended users. Manufacturers should consider how they will demonstrate this requirement has been met. In particular for devices with lay person users, it seems likely that user testing of the labelling and instructions would be applied to demonstrate compliance. Usability standards/technical reports (guidance) such as EN 62366-1, EN TR 62366-2, EN 60601-1-6 can be helpful with this requirement. Also, the home healthcare environment standard for medical electrical equipment EN 60601-1-11 may be helpful in meeting this requirement.

SPR 23.1 (b) which identifies that the information on the label shall be provided on the device itself (if practicable and appropriate) is not new to the MDD, and aligns with MDD ER 13.1. This requirement has no counterpart in the AIMDD, as it may not often be practical for implantable devices; however, AIMDD ERs 11 and 12 stipulate requirements for identification directly on the device.

SPR 23.1 (c) requires that labels be human-readable although this may be supplemented by machine-readable information such as bar codes or RFID. This requirement has not been explicitly stated before in the Directives, although the expectation by default has always been that the required information be in a human readable format.

SPR 23.1 (d) states that an IFU must accompany the devices (if required to use safely). This requirement is not new and aligns with MDD ER 13.1 and AIMDD ER 15.

SPR 23.1 (e) states that when multiple devices are provided to a single user or location, a single copy of the IFU may be provided if agreed with the purchaser, so long as additional copies may be requested and provided free of charge. The AIMDD has not previously allowed for this (AIMDD ER 15). This SPR may also clarify ambiguity in the MDD requirements (MDD ER 13.1) for providing IFU in a shipping box versus each individual product package; so long as users agree, providing a single IFU with multiple devices shipped together will be acceptable per this MDR requirement.

SPR 23.1 (f) allows IFU to be provided electronically, only in accordance with existing EU Regulation 207/2012. In a recent update the MDR added the text 'or in any subsequent implementing rules adopted pursuant to this Regulation' allowing for future implementing rules that will be established for this Regulation.

SPR 23.1 (g) generally aligns with MDD ER 13.3 (k); 13.6 (e), (f), (h), (k) - (o) and AIMDD ER 15 relative to the inclusion of residual risks as warnings, precautions, limitations, or contraindications in the information provided to the user. This also aligns with MDD ER 2 which requires that users should be informed of the residual risks and AIMDD ER 15 requiring that undesirable side effects be included in the IFU.

SPR 23.1 (h) largely aligns with MDD ER 13.2 relative to the use of internationally recognized symbols and colors from harmonized standards but also references conformity to 'CS' (see text box above) if they exist. The latter is a new concept with the introduction of this Regulation. Although harmonized standard EN 980:2008 exists for medical device symbols, additional symbols can be found in other standards not currently harmonized (at time of writing) under the MDD, such as ISO 15223:2016 (symbols for medical device labels), IEC 60417 (graphical symbols for equipment), IEC 60878 (graphical symbols for medical electrical equipment) and others. These international standards can be sources to establish 'state of the art' for manufacturers in the absence of appropriate symbols in the main harmonized standards or existing CS.

SPR 23.2: Label requirements

SPR 23.2 defines the requirements for what should be included on the product label. Many of the requirements can be directly mapped to subparts of MDD ER 13.3 or AIMDD ER 14. Those requirements which are essentially unchanged will not be discussed here in detail. Like the AIMDD, the MDR now defines particular requirements for labels on the sterile pack in SPR 23.3 (discussed below). Unlike the AIMDD, the balance of the labelling requirements is not stipulated for the 'sales' or 'trade' packaging. It can be concluded that many of the labelling requirements in SPR 23.2 may be on the outer or inner package for devices with an inner 'sterile pack,' but the requirements in SPR 23.3 must, at a minimum, be on the sterile package. The biggest changes to the label requirements are entirely new device aspects to be identified; these generally do not have currently harmonized symbols available to denote the information and it is currently unclear whether a symbol or CS (see text box above) will be developed, although this seems likely.

Labelling requirements which are generally unchanged from the Directives will not be discussed in detail below, but cross-references between MDR and MDD/AIMDD requirements can be found in the table in Appendix 1.

SPR 23.2 (a): Can be correlated to MDD ER 13.3 (b) and AIMDD ER 14.2, Part 2.

SPR 23.2 (b): Can be correlated to MDD ERs 13.3 (b) and 13.4, and AIMDD ER 14.2, Parts 2 and 3.

SPR 23.2 (c): Can be correlated to MDD ER 13.3 (a) and AIMDD ER 14.2, Part 1.

SPR 23.2 (d): This SPR can be correlated to MDD ER 13.3 (a) and AIMDD ER 14.2, Part 1. It is noted, however, that the MDD previously allowed for the authorized EU representative to be on the label, outer package, or the IFU (it was not required to be in all places). In contrast, the MDR requires the EU representative to be on both the label, and does not explicitly require it to be on the IFU.

SPR 23.2 (e): An indication if the device contains or incorporates a medicinal substance including a human blood/plasma derivative, tissues or sales of human or animal origin, or derivatives of animal tissue as defined in EU Regulation 722/2012. While IFUs are already expected to contain descriptive information and specific information on any immunological risks with respect to animal tissue, the requirement for the label is new for all but the human blood derivatives, compared to the Directives (MDD ER 13.3(n), AIMDD ER 14.2 Part 11) There are currently no harmonized standards for these symbols to denote the presence of a medicinal substance, animal tissue, etc., and it seems probable that this will be defined in future along with other symbols to accompany the MDR. New symbols will make meeting this requirement more feasible without the burden of multiple translations on the label or the confusion of various manufacturer-generated symbols for these aspects, which are the otherwise available options.

SPR 23.2 (f): Labelling information in accordance with SPR 10.4.5. This refers back to the CMR and endocrine disruptors as outlined in SPR 10.4.1. For the invasive and other devices as defined in SPR 10.4.1, and the CMR/endocrine disruptors over 0.1 per cent by weight, the specific labelling requirements are defined in SPR 10.4.5 and are linked from SPR 23.2 (f). These requirements go much further than the current requirement in MDD ER 7.5 to indicate the presence of phthalates on the unit packaging. There is no corresponding requirement in the AIMDD.

SPR 23.2 (g): Can be correlated to MDD ER 13.3 (d). The AIMDD does not require lot or serial numbers on the label but has already required such traceability information to be identified in AIMDD ER 11.

SPR 23.2 (h): Unique Device Identification (UDI) is being implemented in the MDR, and the UDI carrier per Article 27(4) and Annex VII Part C is required to be on the product label and all higher level packaging except for the shipping container level per Article 27(4).

SPR 23.2 (i): Can be generally correlated to MDD ER 13.3 (e) and AIMDD ER 14.2, Part 9. The SPR wording for expiration dates here includes the time limit for 'using' or 'implanting' the device safely, combining wording from the two Directives.

SPR 23.2 (j): Can be correlated to MDD ER 13.3 (l). A clarification was added to that date of manufacturer may be included as part of the lot number or serial number, provided the date is clearly identifiable. There is a harmonized symbol for 'date of manufacture' available for use, which would be one way to clearly identify the date as such if included as part of the lot number or serial number; use of available harmonized symbols is expected unless appropriately justified. There is no corresponding requirement in the AIMDD.

SPR 23.2 (k): Can be correlated to MDD ER 13.3 (i). There is no corresponding requirement in the AIMDD.

SPR 23.2 (l): Can be correlated to MDD ER 13.3 (c) and 13.3 (m). There is no corresponding requirement in the AIMDD.

SPR 23.2 (m): While similar to MDD ER 13.3 (k), this requirement is now much more detailed. SPR 23.2 (m) requires that the label include any warnings or precautions that 'need to be brought to the immediate attention of the user.' It is acknowledged that this may be kept to a minimum where more detailed information shall appear in the IFU, taking into account the intended users. Manufacturers may consider in the risk management process what warnings or precautions should be 'immediately' communicated on the label to justify inclusion or exclusion of information per this requirement. There is no corresponding label requirement in the AIMDD.

SPR 23.2 (n): Can be correlated to MDD ER 13.3 (n). There is no corresponding requirement in the AIMDD.

SPR 23.2 (o): This requirement is new from both Directives and addresses the reprocessing of single use devices. If a device is a reprocessed single use device, this must be indicated along with the number of reprocessing cycles performed and any limitation on the number of reprocessing cycles. As with Requirement (e) above in this section, harmonized standards for these types of symbols do not currently exist for this new labelling requirement.

SPR 23.2 (p): Can be correlated to MDD ER 13.3 (g) and AIMDD 14.2 Part 6.

SPR 23.2 (q): 'An indication that the device is a medical device' is listed as a requirement for all devices, along with the provisions in Part (q) for clinical investigation devices. As with SPR 23.2 (e) and SPR 23.2 (o), a harmonized standard for this symbol does not currently exist and it is unclear what form this 'indication' should take. If the device is 'exclusively for clinical investigation,' those words must be included (correlates to MDD ER 13.3 (h) and AIMDD ER 14.2 Part 5).

SPR 23.2 (r): For devices composed of substances absorbed or locally dispersed, the 'overall qualitative composition' and 'quantitative information on the main constituents responsible for achieving the principal intended action.' This requirement has no correlation to the Directives.

SPR 23.2 (s): Serial number for active implantable devices. This requirement for the label itself is not present in the current AIMDD text. For other implantable devices, the serial number or batch number must be included. For all MDD devices including implantables, this has previously been captured in MDD ER 13.3 (d). It is noted that the second part of this requirement (for non-active implantable devices) appears slightly redundant to SPR 23.2 (g) which requires a lot or serial number for all devices.

SPR 23.3: Sterile package label requirements

The separation of requirements for the sterile package label (as opposed to simply the device label) is new in SPR 23.3 in comparison to the MDD, but the requirements are similar. However, this is an existing concept in the AIMDD and corresponds to AIMDD ER 14.1. For AIMDD manufacturers, all but SPR 23.3 (j) can be mapped to AIMDD ER 14.1 with some rearrangement of the order.

For MDD manufacturers, most requirements in this list will also be familiar as a subset of existing labelling requirements and the list in SPR 23.2.

The only requirement not already captured for the general label requirements in SPR 23.2 is SPR 23.3 (j), an instruction to check the IFU for what to do if the sterile package is damaged or unintentionally opened before use.

SPR 23.4: Instructions for Use

The list of particulars for inclusion in the device IFU is generally expanded. As with the labels, many IFU requirements are familiar from the Directives but some are new to the MDR. As with the labelling discussion, the requirements which are essentially unchanged for IFU will not be discussed here in detail.

SPR 23.4 (a): This requirement references back to most of the labelling requirements for inclusion in the IFU. This is similar to the current requirements of MDD ER 13.6 (a) and AIMDD ER 15 Indent 2. Of the referenced requirements, most are already required for inclusion in IFU. One exception is in SPR 23.2 (e), requiring clear identification of not only medicines as in the current MDD, but of tissues or cells of human or animal origin or animal tissue derivatives contained in the device. Another addition is SPR 23.2 (f), information about CMR and endocrine-disrupting substances, which goes beyond the current requirements of MDD ER 7.5. The last addition is SPR 23.2 (r), particulars of substances absorbed or locally dispersed, which is new to the labelling requirements.

SPR 23.4 (b): Specification of the device's intended purpose in the IFU is required currently as part of MDD ER 13.4 and AIMDD ER 15 Point 2, but this requirement goes further in requiring a clear specification of indications, contraindications, the patient target groups and the intended users.

SPR 23.4 (c, d): Specification of expected clinical benefits and links to the publicly available 'Summary of Safety and Clinical Performance' as defined in Article 32. As mentioned for SPR 23.1, presenting the information on clinical benefits, safety, and clinical performance is new to European IFU requirements. This is a new requirement compared to the Directives.

SPR 23.4 (e): Can be correlated to ER 13.6 (b) and AIMDD ER 15 Part 3.

SPR 23.4 (f): Information allowing the healthcare professional to 'verify if the device is suitable and select corresponding software and accessories.' This corresponds to AIMDD ER 15 Part 4 and more loosely to MDD ER 13.6 (c) on combinations of devices.

SPR 23.4 (g): Information regarding residual risks, including contraindications and undesirable side effects and information to be conveyed to the patient in this regard. As mentioned in SPRs 4 and 23.1, the MDR now explicitly requires that residual risks be identified in the IFU. Many manufacturers are already in this practice per interpretation of the MDD ER 2.

SPR 23.4 (h): This generally correlates to MDD ER 13.6 (p) and does not have a direct counterpart in the AIMDD.

SPR 23.4 (i): Details of preparation or handling including disinfection. If a device requires specific preparation or handling, including disinfection, this is likely already present in the manufacturer's IFU to ensure safe use and mitigate identified use risks. However, this is now explicitly required by the MDR for the IFU in this point.

SPR 23.4 (j): Any special facilities, training, or qualifications for the user must be included in the IFU. This has not been explicitly required but is common in IFU. This can be roughly correlated to or understood from MDD ER 13.6 (a) referring to MDD ER 13.3 (j) and AIMDD ER 15 Part 5.

SPR 23.4 (k): This requirement for device installation is similar to MDD ER 13.6 (d), but adds additional text for information regarding disinfection and cleaning, identification of consumable components, maintenance and methods of eliminating risks for persons installing, calibrating or servicing the devices.

SPR 23.4 (l): Can be correlated to MDD ER 13.6 (g) and AIMDD ER 15 Part 8.

SPR 23.4 (m): Can be correlated to MDD ER 13.6 (h) and does not have a counterpart in the AIMDD as implantable devices would typically be provided already sterile.

SPR 23.4 (n): For reusable devices, the requirement is similar to MDD ER 13.6 (h) Paragraph 1, but additional text is added. The new text refers to re-sterilization 'as appropriate to the Member State,' and requires that information be provided to identify when the device should not be reused, such as a defined number of uses or signs of material degradation. There is no corresponding requirement in the AIMDD. Please refer to your competent authority for further information.

SPR 23.4 (o): This requirement is new versus the MDD but corresponds to AIMDD ER 15, Indent 9. If appropriate, the manufacturer should indicate in the IFU that a device can only be reused if it is reconditioned under the responsibility of the manufacturer to comply with the general SPRs. This appears to be limited to manufacturers' reconditioning of their own devices, and does not include when third parties may possibly be expected to recondition a single-use device.

SPR 23.4 (p): The requirement to list risks of reuse of single-use devices is currently in MDD ER 13.6 (h) and was part of the 'M5 revisions' to that Directive. However, this SPR now further specifies that the information shall be based on a specific section of the manufacturer's risk management documentation, with the technical factors addressed in detail. This should be clearly identifiable in risk management documents for every device. The requirement will likely also lead to an expectation of more device-specific and technical warnings on reuse rather than a general risk of 'infection or contamination,' as some manufacturers currently include in IFUs to address 13.6 (h) Paragraph 2 for a broad range of devices.

SPR 23.4 (q): Though similar to MDD ER 13.6(c), this requirement adds that 'information on any known restrictions to combinations of devices and equipment' be included in the IFU.

SPR 23.4 (r): This SPR is partially aligned with MDD ER 13.6 (j) regarding the requirements for devices emitting radiation for medical purposes. However, in addition to detailed information about the emitted radiation, information about the 'means of protecting the patient, user, or other person from unintended radiation during use' must be included in the IFU.

SPR 23.4 (s): This multi-part requirement outlines information in the IFU needed to brief the patient. Some aspects of this are similar to AIMDD ER 15 part 2 and MDD ER 13.6 (k-m). The information is expanded from the Directives. The second indent has added information to be included regarding exposure to radiation, humidity and temperature with respect to the device. The third intent relates to risks of interference (such as electromagnetic interference) more specifically than either of the Directives. The fourth indent of SPR 23.4 (s) requires information to brief patients if the device administers medicinal products, tissues or cells of human or animal origin, tissue derivatives or biological substances, regarding any limitations or incompatibility in the delivered substances. The fifth indent relates more generally to any warnings, precautions or limitations related to the medicinal substance or biological material incorporated into the device. The last indent is new and relates to precautions from substances of concern (CMR substances or endocrine-disrupting substances), as well as substances that could result in a sensitization or allergic reaction; this has not previously been a requirement in IFUs, although it may already been included in IFUs for devices where it is relevant as part of risk mitigation and disclosure of residual risks and possible adverse events.

SPR 23.4 (t): New requirement which is again relevant to the new category of substances (or combinations) absorbed by or locally dispersed in the body. For these devices, the IFU must contain warnings and precautions relating to the interaction profile and products of metabolism with other devices, medicines, or substances. Contraindications, undesirable side effects and risks relating to overdose must be included.

SPR 23.4 (u): This is a new requirement for implantable devices to include in the IFU information (qualitative and quantitative) on the materials and substances to which patients can be exposed. It is reasonable that this is especially critical for potentially dangerous substances, but the requirement is written such that information on all materials and substances should be included.

SPR 23.4 (v): This requirement is much more explicit that the MDD ER 13.6 (n) of safe disposal of the device, accessories and the consumables used with the device; there is no direct equivalent in the AIMDD. This relates to SPR

14.7, which requires the IFU to include specifically identified and tested procedures for safe disposal of the device and related waste substances. SPR 23.4 (v) includes consideration of items contaminated with potentially infectious substances, including human or microbial hazards, and physical hazards such as sharps. All these items should have been covered by the use of Risk Management under both Directives previously, but these SPRs may lead to more specific information than the generic statements currently in many IFUs.

SPR 23.4 (w): A new requirement for the recurring concept in the MDR of devices 'for use by lay persons.' The IFU must include information on circumstances when the user should consult with a healthcare professional.

SPR 23.4 (x): This is a specific requirement for the devices without a medical purpose as defined in Article 1(2). For these devices, the absence of clinical benefit as well as the risks related to use of the device must be disclosed in the IFU.

SPR 23.4 (y): Can be correlated to MDD ER 13.6 (q) and AIMDD ER 15 Part 14.

SPR 23.4 (z): A notice to the user and/or patient that serious incidents should be reported to the manufacturer and competent authority. While the concept of serious incident reporting/vigilance reporting is not new, it was not previously required to inform users or patients in the IFU that such incidents should be reported. Patient reporting of adverse events would likely be new to manufacturers and may require new procedures and investigation practices. This requirement is likely aimed at increasing reporting to obtain more complete information on adverse event incidents.

SPR 23.4 (aa): Information to be supplied to the patient for an implanted device per Article 18. This requirement for patient information or 'implant card' relates to a common practice which will now be strictly required in the EU. Article 18 includes detailed information on the required contents of the 'implant card and information' to be supplied to the patient.

SPR 23.4 (ab): For electronic programmable systems including software and software as a medical device, the IFU must include information on minimum requirements for hardware, networks, security and protections against unauthorized access, necessary to run the software as intended.

Absent in SPR list: Clinical evaluation, medicinal consultation

The MDR includes a lot of new and detailed information on clinical aspects. The most detailed information is contained in Annex XIV, 'Clinical Evaluation and Post-Market Clinical Follow-Up.' While requirements for clinical evaluation are integral to the new MDR, the requirement to have a clinical evaluation, currently in MDD ER 6a and AIMDD ER 5a, has moved out of the SPR list as such. The requirements for clinical evaluations and post-market clinical follow-up are therefore out of the scope of this white paper review, but are covered in other BSI white papers, bot published and to follow. http://www.bsigroup.com/en-GB/our-services/medical-device-services/BSI-Medical-Devices-Whitepapers/

The requirements and procedure for competent authority consultation on ancillary medicinal substances previously resided in MDD ER 7.4 and AIMDD ER 10. The general procedure under the MDR is unchanged but the details are in Annex IX, Chapter II, Section 5.2 of the MDR and not directly in the SPR list. The specific details of medicinal consultation are therefore out of the scope of this white paper review.

Demonstrating and documenting compliance

Many manufacturers utilize tables or checklists (i.e. ERC) to systematically demonstrate compliance with MDD and AIMDD ERs. While such a document is not explicitly required by the MDR and no format is prescribed, manufacturers may find it useful to take a similar approach (i.e. SPRC) to tracing and documenting compliance with the SPRs. MDR Annex II Section 4 (for Technical Documentation) requires manufacturers to demonstrate conformity with the applicable general safety and performance requirements of Annex I, including an explanation for those which are

not applicable, methods used to demonstrate conformity with all applicable requirements, and the precise identity of the documents offering evidence of conformity. This is more prescriptive and detailed than the Directives which more generally require a 'description of the solutions adopted to fulfill the ERs.' Annex II also requires the Technical Documentation to be readily searchable and unambiguous, and this would also include the SPRC or similar document tracing conformity to the SPRs. Essentially, manufacturers must demonstrate compliance with the applicable SPRs, and clearly denote which SPRs are not applicable; a central document (such as a checklist or table) referencing other documents and data may be a practical way to achieve this.

Conclusions

A full gap analysis of the safety and performance requirements in the new MDR against the ERs in the MDD and AIMDD identifies several new requirements and many areas of increased emphasis and specificity. The word count of the MDR safety and performance requirements has nearly doubled compared to the MDD ERs. Some of the new requirements will represent truly new work required of the manufacturer, while others will align with current practice according to harmonized standards and best practices.

Many 'state of the art' requirements from harmonized standards have been incorporated directly into the Regulation's SPRs. These will have a smaller impact on manufacturer's activities, as many of these requirements are likely being addressed already. However, careful attention to detail is recommended for the requirements most relevant to a manufacturer's own devices.

Manufacturers should read and understand the MDR to prepare for the changes ahead, and check with their notified bodies for consistency or agreement in interpretation.

As with the current ERs, the best approach is likely to first determine which of the new 'safety and performance requirements' will be considered as applicable, and to ensure an appropriate rationale for requirements deemed not applicable. The relevant requirements will then have to be considered with respect to existing documentation, to identify gaps which may need to be addressed. For some of the most novel requirements, manufacturers will have to consider how clearly demonstrate compliance through testing, risk management, and other means. For the expanded labelling IFU requirements, the SPRs must be considered in careful detail to ensure all required information is included.

Appendix 1

Medical Devices Regulation (MDR)

SPR/ER Cross-reference Mapping Guide

Low priority Medium priority High priority

Reference Number			
MDR SPR	MDD ER	AIMDD ER	Other Guidance
1	1, 2, 3	1, 2,6	-
2	2	8	-
3	-	-	EN ISO 14971
4	2	6	-
5	1	-	-
6	4	3	-
7	5	4	EN ISO 11607-2
8	6	5	-
9	-	-	MDR Annex XVI
10.1	7.1	9	ISO 10993 series
10.2	7.2	-	-
10.3	7.3	-	-
10.4	7.5	-	Regulation 1272/2008, Regulation 1907/2006, Regulation 528/2012
10.5	7.6	9	-
10.6	-	-	MDR Annex VIII Rule 19
11.1	8.1	7	-
11.2	-	-	-
11.3	-	-	-
11.4	8.3	7	-
11.5	8.4	-	EN ISO 13485 Sec. 7.5.7 EN ISO 11607-1/-2
11.6	8.5	-	-
11.7	8.6	-	-
Reference Number			
SPR	**MDD**	**AIMDD**	**Other**
11.8	8.7	-	-
12.1	7.4	10	Directive 2001/83/EC; MDR: Annex IX, Ch. II, Sec. 5.2, MDR Annex VIII Rule 14
12.2	-	-	Directive 2001/83/EC
13.1	7.4	10	Directive 2004/23/EC Directive 2002/98/EC
13.2	8.2	-	EN ISO 22442-2 EU Reg 722/2012
13.3	-	-	-

Reference Number			
SPR	MDD	AIMDD	Other
14.1	9.1	9	-
14.2a	9.2	8	-
14.2b	9.2	8	EN 60606-1
14.2c	7.3	-	-
14.2d	-	-	EN 60601-1 ISO 800001
14.2e	7.6	-	-
14.2f	9.2	-	-
14.2g	9.2	8	-
14.3	9.3	-	-
14.4	-	-	-
14.5	14.1	9.1	-
14.6	10.2	-	-
14.7	-	-	-
15	10.1, 10.3	-	Directive 80/181/EEC
16.1a	11.1	-	-
16.1b	11.4	-	-
16.2a	11.2.1	-	-
16.2b	11.2.2	-	-
16.3	11.3	-	-
16.4a	11.5.1	8	2013/59/Euratom
16.4b	-	-	-
16.4c	11.5.2	-	-
16.4d	11.5.3	-	-
17.1	12.1	-	-
17.2	12.2	9, part 7	-
17.3	-	-	-
17.4	-	-	EN 60601-1+A1
18.1	12.1	-	-
18.2	12.2	-	EN 60601
Reference Number			
SPR	MDD	AIMDD	Other
18.3	12.3	-	-
18.4	12.4	-	-
18.5	12.5	-	-
18.6	-	-	EN 60601-1 EN 60601-2
18.7	12.6	-	-
18.8	-	-	-
19.1	-	8	-
19.2	-	9	-

Reference Number			
SPR	MDD	AIMDD	Other
19.3	-	11	-
19.4	-	12	MDR, Article 31
20	12.7	-	EN ISO 14708 EN 45502
20.5	-	-	-
21.1	12.8.1	9	-
21.2	12.8.2	-	-
21.3	12.9	-	-
22	-	-	EN 62366 EN 60601-1-11
23.1a	-	-	EN 62366-1 EN TR 62366-2 EN 60601-1-6
23.1b	13.1	11, 12	-
23.1c	-	-	-
23.1d	13.1	-	-
23.1e	-	-	-
23.1f	-	-	EU Reg 207/2012
23.1g	-	-	-
23.1h	13.2	-	EN 980:2008 ISO 15223:2016 IEC 60417 IEC 60878
23.2a	13.3c	14.2, part 2	-
23.2b	13.3b, 13.4	14.2, part 2 and 3	-
23.2c	13.3a	14.2, part 1	-
23.2d	13.3a	-	-
23.2e	13.3n	14.2, part 11	-
23.2f	7.5	-	-
23.2g	13.3d	11	-
23.2h	-	-	-
23.2i	13.3e	14.2, part 9	-
Reference Number			
SPR	MDD	AIMDD	Other
23.2j	13,3 (l)	-	-
23.2k	13.3i	-	-
23.2l	13.3c, 13.3m	-	-
23.2m	13.3k	-	-
23.2n	13.3f	-	-
23.2o	-	-	-
23.2p	13.3g	14.2, part 6	-
23.2q	13.3h	14.2, part 5	-

Reference Number			
SPR	MDD	AIMDD	Other
23.2r	-	-	-
23.2s	13.3d	-	-
23.3a	13.3c	14.1, part 2	-
23.3b	-	14.1, part 7	-
23.3c	13.3m	14.1, part 1	-
23.3d	13.3a	14.1, part 3	-
23.3e	13.3b	14.1, part 4	-
23.3f	13.3h	14.1, part 5	-
23.3g	13.3g	14.1, part 6	-
23.3h	13.3l	14.1, part 8	-
23.3i	13.3e	14.1, part 9	-
23.3j	13.3i	-	-
23.4a	13.6a	15, part 2	-
23.4b	13.4	15, part 2	-
23.4c	-	-	MDR Art. 32
23.4d	-	-	MDR Art. 32
23.4e	13.6b	15, part 3	-
23.4f	-	15, part 2	-
23.4g	13.6e	15, part 2	-
23.4h	13.6d, p	-	-
23.4i	13.6i	-	-
23.4j	13.3j, 13.6a	15, part 5	-
23.4k	13.6d,	-	-
23.4l	13.6g	15, part 8	-
23.4m	13.6h	-	-
23.4n	13.6h	-	-
23.4o	-	15, part 9	-
23.4p	13.6h	-	-
23.4q	13.6c	-	-
Reference Number			
SPR	MDD	AIMDD	Other
23.4r	13.6j	-	-
23.4s	13.6k - m	15, part 2	-
23.4t	-	-	-
23.4u	-	-	-
23.4v	13.6n	-	-

	Reference Number		
SPR	MDD	AIMDD	Other
23.4w	-	-	-
23.4x	-	-	-
23.4y	13.6q	15, part 1-4	-
23.4z	-	-	-
23.4aa	-	-	-
23.4ab	-	-	-
Absent	6a	5a	MDR Annex XIV
Absent	7.4 - consultation text	10 - consultation text	MDR Annex IX, Chapter II, Section 5.2

Please note: This document is a guide to help you to map the changes for the MDR. This is not an exhaustive list and whilst BSI believes that it accurately reflects the regulatory environment at the time of publication, you should be aware that this is complex and can change. Therefore, this table is not to be considered as providing any legal advice and is not to be used as a substitute to reading the regulations directly or seeking advice from a qualified expert.

Safety and Performance White paper author and reviewer biographies

Authors

Laurel Macomber, Senior Manager, Medical Operations, DePuy Synthes
Laurel has over 25 years' experience in the medical device industry including 7 years at BSI as a Notified Body Product Expert and experience in R&D, program management, and QMS development. She has worked on orthopaedic, dental, neurosurgical, cardiovascular, general surgery, and spinal devices; including combination devices incorporating biologics and drugs. Laurel earned an M.S. in Bioengineering from Clemson University and was awarded a postgraduate fellowship from the National Institute on Disabilities and Rehabilitation Research at MIT. Laurel also holds a Six Sigma Black Belt and Project Management Professional (PMP) and Regulatory Affairs Certifications (RAC).

Alexandra Jantzen Schroeder, PhD, Product Expert and Scheme Manager for Vascular Devices at BSI
As a product expert for BSI, Alexandra manages CE Marking certification schemes and is a technical reviewer for vascular devices including stents and other catheter-based devices. She has been with BSI since 2014. Prior to BSI, Alexandra worked for several years in Product Development of stents and other vascular devices at Cook Medical. She earned a PhD in Biomedical Engineering from Duke University, where she researched methods for seeding vascular endothelial cells onto metallic stent surfaces and fluid dynamics of stents. Alexandra holds 3 US patents for medical devices and is a contributing author in 10 peer-reviewed research publications.

Expert Reviewers

Mika Reinikainen, LL.M., MBA, Medical Device Regulatory Affairs Consultant
Mika focuses on regulatory interpretation, borderline issues, classification, post-market surveillance and authorised representation as well as negotiations with competent authorities and Notified Bodies. He has more than 30 years of experience in the European medical device field: as regulatory affairs manager in industry (Pfizer Hospital Product Group of companies), as healthcare legal counsel (Hogan & Hartson) and as regulatory consultant (Medical Technology Consultants Europe, Quintiles and Abnovo). He headed the working group that developed the original medical device classification system and is currently a member of the Commission's Borderline and Classification Working Group.

Ronald Rakos, PhD, MBA, RAC, Operational Effectiveness and Development Lead, Vascular Medical Devices
Ronald has spent over 12 years working in the medical technology industry and 10-years at BSI. Where has held a number of positions from Product Specialists to Global Head for the Vascular Medical Devices team; he is currently the Operational Effectiveness and Development Lead for the Vascular team. Ron has applied his extensive knowledge of the medical device product development process to the evaluation and assessment of technical documentation for diverse vascular applications His expertise includes; stents, catheters and associated accessories, vascular grafts, polymer processing, product and process validation and computational analysis. Ron holds a PhD in Chemical Engineering from Stevens Institute of Technology and a MBA in Finance from Rutgers University.

Maritza Carballo, Global Head of Vascular Devices for BSI
Maritza currently leads the vascular technology team focused on providing CE certification services to BSI clients. She has spent the last 9 years conducting CE marking technical reviews of vascular devices and managing a portfolio of clients. Prior to BSI, she spent 12 years in various roles in product development that included drug eluting coronary and peripheral stents, vascular grafts, embolic coils, and other cardiovascular devices and managed commercialization teams through all phases of development including clinical trials. Maritza earned an M.S. in Mechanical Engineering from Florida International University and was awarded a National Science Foundation Fellowship.

Advisory Panel

Leo Eisner, Principal consultant of Eisner Safety Consultants
Leo's firm specializes in helping clients through product safety, international regulatory and quality system processes. Leo is a Notified Body Auditor for NEMKO (previously for NSAI & TÜV PS). Leo is the convener of IEC SC62D JWG9 (IEC/ISO80601-2-58) & a committee member of US TAG for TC62, SC62A & SC62D. Leo is a registered professional engineer in safety and has 28 years' experience in product safety. Leo is a member of RAPS, AAMI, ASQ, & IEEE. He's manager of the LinkedIn discussion group IEC 60601 Series – Medical Electrical Equipment.

Pete Philips, Director of the Surgical Materials Testing Laboratory (SMTL) Pete is the Director of the Surgical Materials Testing Laboratory (SMTL), based in Bridgend in South Wales, which is funded by the Welsh Government to test medical devices for the Welsh NHS and to provide technical advice on medical devices. He has worked in the medical devices field for 30+ years, and sits on a number of BSI, CEN and ISO medical device committees and groups. He chairs the Welsh Non-Luer Connectors Reference Group (WNCRG) for Welsh Government, which is coordinating the implementation of new ISO compliant non-Luer connectors across the Welsh NHS, and represents Welsh Government on medical devices on various other groups.

Published white papers

The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices: An Overview of the Likely Outcomes and Consequences for the Market, Gert Bos and Erik Vollebregt

Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance, Hassan Achakri, Peter Fennema and Itoro Udofia

Effective Post-market Surveillance – Understanding and Conducting Vigilance and Post-market Clinical Follow-up, Ibim Tariah and Rebecca Pine

What You Need to Know About the FDA's UDI System Final Rule, Jay Crowley and Amy Fowler

Engaging Stakeholders in the Home Medical Device Market: Delivering Personalized and Integrated Care, Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine

Negotiating the Innovation and Regulatory Conundrum, Mike Schmidt and Jon Sherman

The Growing Role of Human Factors and Usability Engineering for Medical Devices: What's Required in the New Regulatory Landscape? Bob North

ISO 13485: The Proposed Changes and What They Mean for You, Bill Enos and Mark Swanson

The Differences and Similarities between ISO 9001 and ISO 13485, Mark Swanson

How to Prepare for and Implement the Upcoming MDR: Dos and Don'ts, Gert Bos and Erik Vollebregt

How to Prepare for and Implement the Upcoming IVDR: Dos and Don'ts, Gert Bos and Erik Vollebregt

Planning for Implementation of the European Union Medical Devices Regulations – Are you prepared?, Eamonn Hoxey

Cybersecurity of Medical Devices, Richard Piggin

The European Medical Devices Regulations – what are the requirements for vigilance reporting and post-market surveillance? Eamonn Hoxey

Forthcoming white papers

Do you know the requirements and your responsibilities for Medical Device Vigilance Reporting? A detailed review on the requirements of MDSAP participating countries in comparison with the European Medical Device Regulation 2017/745, Cait Gatt and Suzanne Halliday

Clinical Data – Moving away from Clinical Equivalence in Europe (working title)

Modifying, Creating and Maintaining Technical Documentation (working title)

Managing changes to a QMS (working title)

Nanotechnology – what does the future look like for the medical devices industry? (working title)

About BSI Group

BSI (British Standards Institution) is the business standards company that equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. Formed in 1901, BSI was the world's first National Standards Body and a founding member of the International Organization for Standardization (ISO). Over a century later it continues to facilitate business improvement across the globe by helping its clients drive performance, manage risk and grow sustainably through the adoption of international management systems standards, many of which BSI originated. Renowned for its marks of excellence including the consumer recognized BSI Kitemark™, BSI's influence spans multiple sectors including aerospace, construction, energy, engineering, finance, healthcare, IT and retail. With over 70,000 clients in 150 countries, BSI is an organization whose standards inspire excellence across the globe.

BSI is keen to hear your views on this paper, or for further information please contact us here:
julia.helmsley@bsigroup.com

This paper was published by BSI Standards Ltd

For more information please visit:
http://www.bsigroup.com/en-GB/our-services/medical-device-services/BSI-Medical-Devices-Whitepapers/

BSI Group Headquarters
389, Chiswick High Road
London W4 4AL
United Kingdom

T: +44 (0) 845 086 9001
E: cservices@bsigroup.com
bsigroup.com

BSI UK
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes MK5 8PP
United Kingdom

T: +44 (0) 845 080 9000
E: MK.customerservices@bsigroup.com
bsigroup.com

BSI Group America Inc
12950 Worldgate Drive
8th Floor Monument II
Herndon
VA 20170
USA

T: +1 800 862 4977 / 703 437 9000
E: inquiry.msamericas@bsigroup.com
bsiamerica.com