Flags of the member states of the EU

How to prepare for and implement the upcoming MDR – Dos and don'ts

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Introduction

In the previously published white paper, *The proposed EU regulations for medical and in vitro diagnostic devices: An overview of the likely outcomes and the consequences for the market*, a summary was given of the legislative changes likely to be brought about by the new EU Medical Devices Regulation (MDR) and IVD Regulation (IVDR). Both regulations are in the final stages of the legislative procedure and are estimated to finish sometime in 2016, allowing them to come into effect by the end of 2016, or early 2017. Some time would be needed to polish the agreed text and have it translated into the official EU languages.

In contrast to the previous white paper, this white paper will provide information on the impact on manufacturers and is based on the tables featured at the end of the MDI chapters. These tables provide a checklist for MDR preparation, based on our current understanding of MDR. The checklist provides a comprehensive list of actions currently envisaged for the manufacturer before, during and after the transitional period of the MDR, for each chapter of the MDR and its annexes. The IVDR will be discussed in the same way in a separate white paper.

In order to provide context to the checklist, each table is preceded by a short discussion of changes for that respective chapter in the MDR. The full table is listed in the Appendix.

Chapter I – Definitions

A significant number of the definitions may or will change, resulting in products that are currently not classified as medical devices or accessories under the MDD, now included in the scope of the MDR. Examples are the enlarged scope of the definition of accessories that will include devices that specifically or directly assist another device in its intended purpose, the changed definition of custom-made devices that excludes devices that are mass-produced by means of industrial manufacturing processes, and the inclusion of products based on human cell or tissue derivatives. Also, the MDR will apply to non-medical devices with a risk profile similar to medical devices (such as cosmetic implants, contact lenses and cosmetic laser products), which will be included in a list in Annex XV to the regulation.

The MDR now applies to some non-medical devices, such as contact lenses

Subject	Before coming into force	During	After
Chapter I Definitions	Check if cosmetic implants or other products are on Annex XV list	Look out for Common Specifications (CS) for Annex XV devices and implement them	
	Check if devices fall in enlarged scope of 'accessory'	Obtain CE mark for accessory under new regime	Obtain CE mark for accessory under new regime
	Check if custom device is still custom device under new definition	Obtain CE mark if changed to regular medical device	
	Products specifically intended for the cleaning, disinfection or sterilization of medical devices and devices for the purpose of control or support of conception will be considered medical devices		
	Make gap assessment for information required for CE marking of devices concerned	Develop and implement transition strategy for devices concerned into CE marking, generate information needed for CE marking	Obtain CE mark for devices concerned under new regime
	Standalone software is no longer classified as active medical device: revisit classification of software currently on the market as medical device and make gap assessment for additional technical file requirements for software classified in higher risk class	Amend technical files for software in accordance with requirements for higher risk class, have software CE marked by notified body if class IIa or higher	Apply classification rules for new software
ANNEX XV LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE	Identify Annex XV candidate devices in company's portfolio Watch for CS becoming available for devices concerned Start building up technical documentation and if necessary quality management system (QMS)	CE mark Annex XV devices using CS	

New to the MDR is the instrument of Common Specifications (CS). These can be adopted by implementing acts where no harmonized standards exist or where relevant harmonized standards are not sufficient. They can be adopted in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II, the clinical evaluation and post-market clinical follow-up (PMCF) set out in Annex XIII or the requirements regarding clinical investigation set out in Annex XIV. Also, the new mechanism of CS will be used to provide design requirements for the Annex XV products.

Chapter II – Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement

This chapter contains a number of major changes that will impact on the existing quality system and its resources, such as:

- the obligation to have a person responsible for regulatory compliance available within the organization. While there is no guidance on the subject yet, 'have available within the organization' does not seem to indicate that the person concerned must be an employee of the organization, and that a consultant or other external resource would also fulfil this requirement. The Council's General Approach text of the MDR specifically states that the responsible person may or may not be an employee of the organization.
- a supply chain regime that will necessitate changes to current distribution and other supply chain agreements. Each actor in the supply chain will have its own regulatory responsibility (e.g. a duty to check compliance of the device and a duty to initiate corrective action), a big change from the current situation; and
- the liability of the various operators, including the authorized representatives (ARs).

The MDR will feature a relabelling and repackaging regime similar to the regime for relabelling and repackaging developed in the case law of the European Court of Justice for medicinal products.

A much-discussed item still on the table is a mandatory product liability insurance for both manufacturers and ARs (in the latter case accompanied by product liability being imposed on ARs as well), which is expected to cause many ARs to cease activities. If this requirement is adopted for ARs, many manufacturers may need to change their AR as a result of them ceasing activity.

Another hotly debated item is the reprocessing of single-use devices foreseen in Article 15. Each of the political actors made very different proposals. The Commission proposed that reprocessing would be permitted but that member states may prohibit it locally. The Parliament wanted to make reprocessing the standard of care, imposing a burden of proof on industry to provide justification if and why specific devices cannot be reprocessed. Finally, the Council aligned with the Commission but wanted an exception for reprocessing in healthcare institutions. Given the wide gap between the respective sides of the debate, it is very difficult to predict at this stage what the final provision in the MDR will look like.

Subject	Before coming into force	During	After
Chapter II Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement	Assess potential effect of reprocessing and home brews under new hospital produced (so called 'home-brew') devices rules on company business model	Monitor compliance of hospitals with reprocessing and home brews under new hospital produced devices rules	Monitor compliance of hospitals with reprocessing and home brews under new hospital produced brew devices rules (task of national authorities)

Continued

Subject	Before coming into force	During	After
		Manufacturers must establish, execute, maintain and document a system for risk management as described in Section 1a in Annex I	
		Manufacturers must conduct a clinical evaluation in accordance with the requirements set out in Article 49 and Annex XIII, including PMCF	
	Article 5: assess medical devices provided as service via internet	CE mark device as service under new regime	
	Assess own brand labelling consequences of the requirements that a full technical file must be present at each manufacturer (Article 8 (4))	Change business and certification setup into virtual contract manufacturing, or get all required contracts to access key documentation from original equipment manufacturer (OEM) in place	
	Review new manufacturer responsibilities and make gap assessment against QMS	Amend and implement amended QMS Apply QMS optionally to devices placed on the market in transitional period	Apply amended QMS
	Make gap assessment against new recall requirements (Article 8 (8)) Amend procedures and distribution agreements – adopt new requirement '[8a. Manufacturers shall have a system for reporting of incidents and field safety corrective actions as described in Article 61]'		
	Make gap assessment against new QMS criteria in Article 8 (5); amend procedures	Implement amended QMS; consider revising directly into new ISO 13485 at the same time	
	Article 8 (13): mandatory insurance for product liability, monitor developments	Purchase and maintain relevant insurance	Maintain relevant insurance

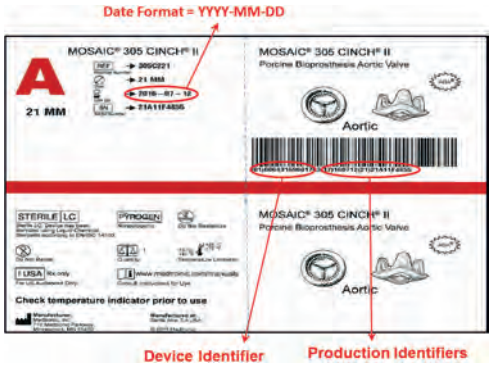
Continued

Subject	Before coming into force	During	After
	New AR requirements Articles 9–10 – amend AR agreement and procedures – expect AR renegotiations or AR to cease activity if liability requirements are adopted	Ensure continued access to AR services when relevant	
	Review autonomous general obligations of importers and distributors (Articles 11–12), e.g. verify compliance of the device, inform competent authority of non-compliance of the device and implement corrective action and amend contracts accordingly	Implement standard operating procedures (SOPs), amend agreements in supply chain	
	Article 13: select and mandate candidate for person responsible for regulatory compliance	Make and keep available in the organization a person responsible for regulatory compliance; ensure training and where appropriate take out personal liability insurance	Keep available in the organization a person responsible for regulatory compliance
	Prepare for new relabelling/ repackaging regime (Article 14), draft SOP for new regime	Implement and apply SOP	Apply SOP
	Article 15: new regime for reprocessing – design traceability that can show if an incoming complaint is about a new or reprocessed single-use device.	Determine what member states will allow reprocessing Implement traceability that can show if an incoming complaint is about a new or reprocessed single-use device Ensure any reprocessing results in patient safety to stay on level of first time use	Ensure any reprocessing results in patient safety to stay on level of first time use Continue to monitor changed allowance per country
	Implant card (Article 16 and implementing acts)	Define system of implant cards, or alternative allowed systems	
	Declaration of conformity (DoC) model (Article 17, Annex III) – check for gaps against current model used	Amend existing DoCs upon transfer per product (group) into the new requirements aligned with transfer plan agreed with notified body	Use MDR provided model of DoC
	Article 21: parts manufacturers to ensure that the part does not adversely affect the safety and performance of the device	Parts manufacturers must generate supporting evidence for this Supporting evidence should be made available to the competent authorities of the member states	Parts manufacturers to generate supporting evidence for each new part placed on the market and to be kept available to the competent authorities of the member states

Chapter III – Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices

The EU will rely heavily on the new version of the European databank on medical devices (EUDAMED) currently under construction for traceability, registration of devices and publication of information concerning medical devices on the EU market. The database will be accessible to manufacturers and for the first time, healthcare professionals, end users and the general public will have access to certain parts of the information in EUDAMED. Manufacturers will need to prepare for and implement Unique Device Identifiers (UDIs) for all of their devices, although UDI will be implemented in phases based on the risk classes of the products, eventually leading to all devices requiring a UDI.

Manufacturers will need to provide a summary of safety and clinical performance for class III devices and also for implants of lower classification, which will be a major effort. This summary must include among other things the intended purpose of the device, indications and contra-indications, reference to standards and CS, a summary of clinical evaluations and suggested profile and training of users.



Example UDI label
© US Food and Drug Administration website, Medical Devices, Unique Device Identification

Subject	Before coming into force	During	After
Chapter III Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices	UDI (Article 23 (1)): distributors and importers shall co-operate with the manufacturer or authorized representative (AR) to achieve an appropriate level of traceability of devices – implement changes to distribution agreements	Implement changes to distribution agreements and SOPs	

Continued

Subject	Before coming into force	During	After
	Article 23 (2): for devices, other than custom-made or investigational devices, economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 8(4): (a) any economic operator to whom they have supplied a device; (b) any economic operator who has supplied them with a device; (c) any health institution or healthcare professional to whom they have supplied a device. – implement and improve traceability	Put traceability systems in place in supply chain, where possible based on UDI	
	Article 24 (3): assign UDI to device and higher levels of packaging and (24 (4)) place that on the label and higher levels of packaging and (24a–c and (5)) keep UDI administration for reporting and tech file	Choose type of UDI system to be applied, in line with global requirements towards UDI	
		If possible, manufacturers may (Article 24b) apply new process for registration of devices prior to placing on the market	Article 24b: apply new process for registration of devices prior to placing on the market
		When implemented, companies may apply process for registration of manufacturers, and ARs and importers, to obtain a single registration number to identify them for the purposes of UDI and traceability	Article 25a: apply process for registration of manufacturers, ARs and importers, single registration number
	Article 26: identify information that must be reflected in summary of safety and performance for each device and conceive plan for generating summaries for each class III and implantable device	Article 26: execute plan for producing summaries for each device Make available summaries for implantable and class III certified under MDR	Article 26: draw up and make available summary of safety and clinical performance for class III and implantable devices, other than custom-made or investigational devices

Continued

Subject	Before coming into force	During	After
		If available, Article 27: enter data into EUDAMED	Article 27: enter data into EUDAMED
ANNEX V INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS	Perform gap analysis of information for EUDAMED database and for UDI purposes Prepare for implementation for EU-UDI	Implement EU-UDI for existing and new devices and register them in EUDAMED database	Use EU-UDI and register new devices in EUDAMED

Chapter IV – Notified bodies

Notified body supervision will change considerably and all notified bodies will need to apply for a new designation during the transitional period. It is currently expected that as a result, a significant number of notified bodies (estimated at 50%) may not be re-notified at all or may not be notified for the same scope under the new regulation. Consequently, manufacturers must be aware that they may need to change notified body and act accordingly if their current notified body is not able to support the manufacturer anymore.

The process of re-designation will take up the first part of the transitional period, as the designation criteria are still to be fully defined, and the process of periodic joint assessments by teams of member states and commission services will be resource-heavy.

Subject	Before coming into force	During	After
Chapter IV Notified bodies	Make assessment of notified body's potential to be re-notified under new system	Re-notification to be timely; with long delays in re-notification, consider alternative plans	
	Agree re-assessment plan with current notified body or agree transition plan to new notified body if necessary		
		Article 36: analyse and implement new transition procedures for dealing with consequences of changes in designation and cessation of notified bodies	
ANNEX VI MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES	Contact notified body to discuss if it can meet the new requirements and prepare for transition if needed	Notified body may or may not be re-notified under new criteria; move to new notified body in case notified body not re-notified or has scope restricted as to not support devices concerned any longer	
ANNEX XII MINIMUM CONTENT OF CERTIFICATES ISSUED BY A NOTIFIED BODY	No action required by manufacturer	No action required by manufacturer	No action required by manufacturer

Chapter V – Classification and conformity assessment

The classification rules will change for certain devices, which will impact on affected devices currently on the market. These devices may need to be recertified in another – typically higher – risk class. This will impact particularly nanotechnology and substance-based medical devices, specific orthopaedic implants (spinal disk replacements), re-usable surgical instruments and life-saving active medical devices such as an automated external defibrillator (AED).

Changes in the conformity assessment rules will impact existing quality systems and will also require manufacturers to revisit the structure and content of current technical files. For example, the regulation will feature new essential safety and performance requirements (the current Essential Requirements) and a mandatory technical file structure and content. Focus on the review of lower risk devices will be much stronger on clinical evaluation, and for lower risk products.

The classification rules will change for certain devices such as reusable surgical instruments

Subject	Before coming into force	During	After
Chapter V Classification and conformity assessment	Perform a gap analysis of all devices on the market against new classification rules and make transition plan if classification necessitates new conformity assessment, class II implants may be subject to additional clinical scrutiny procedure (Article 42 (2a))	Implement transition plan for reclassified devices	

Continued

Subject	Before coming into force	During	After
		Apply new conformity assessment procedures to devices already on market and optionally to new devices to be placed on the market Select devices which have documentation to support the new essential principles	Apply new conformity assessment procedures to devices
	Article 42: make QMS gap analysis against the new rules	Apply new QMS optionally in case of new devices to be placed on the market	Apply new QMS in case of new devices to be placed on the market
			Article 46: conclude tripartite transition agreement with outgoing and incoming notified body in case of voluntary change of notified body
	Do gap assessment of consequences of new substance-based devices rule 21 (class IIb default, class IIa in case on skin, class III if systematically absorbed)	Work on reclassification where appropriate	Apply new classification rule 21
	Do gap assessment for consequences of spinal implants reclassification (spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are in class III with the exception of components such as screws, wedges, plates and instruments, rule 8)	Work on reclassification where appropriate	Apply new classification rule 8
ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	Gap analysis of consequences of changed 'essential requirements' for recertification of existing devices (rule 21, Annex XV, new software requirements) Gap analysis of requirements for new devices	Gap analysis of consequences of changed 'essential requirements' for recertification of existing devices (rule 21, Annex XV) Gap analysis of requirements for new devices	

Continued

Subject	Before coming into force	During	After
ANNEX II TECHNICAL DOCUMENTATION	Gap analysis of existing technical files against new technical file requirements	Amend existing technical files against new technical file requirements and recertification based on amended technical file	Use new technical file requirements
ANNEX III EU DECLARATION OF CONFORMITY	Gap analysis of existing DOC against new DOC requirements	Amend existing DOC against new DOC requirements and recertification based on amended technical file	Use new DOC requirements
ANNEX IV CE MARKING OF CONFORMITY	No changes	No changes	No changes
ANNEX VII CLASSIFICATION CRITERIA	Analyse devices under new classification criteria to determine if they will be reclassified	Recertification of existing devices under new classification rules	Apply new classification rules to new devices
ANNEX VIII CONFORMITY ASSESSMENT BASED ON FULL A QUALITY MANAGEMENT SYSTEM ASSURANCE AND DESIGN EXAMINATION	Perform gap analysis between current full QMS and new full QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS	Apply new QMS
ANNEX IX CONFORMITY ASSESSEMENT BASED ON TYPE EXAMINATION	Perform gap analysis between current type examination QMS and new type examination QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS	Apply new QMS
ANNEX X CONFORMITY ASSESSEMENT BASED ON PRODUCT CONFORMITY VERIFICATION	Perform gap analysis between current product verification QMS and new product verification QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS	Apply new QMS
ANNEX XI CONFORMITY ASSESSMENT PROCEDURE FOR CUSTOM-MADE DEVICES		Apply procedure for custom-made devices optionally to devices in scope	Apply procedure for custom-made devices in scope

Clinical evidence for existing devices will need to be updated

Chapter VI – Clinical evaluation and clinical investigations

The MDR will put in place a European regimen for clinical investigations that will replace the diversity of member state regulation in the EU. It will introduce many new concepts relating to clinical evaluation and clinical investigation, as well as a mandatory PMCF and periodic safety update reports (also known as PSURs). This will require a thorough review of the manufacturer's clinical strategy and PMCF plans. Compliance with the current MEDDEVs on clinical requirements is unlikely to be sufficient for compliance under the new rules. Manufacturers will need to revise not only their clinical strategy for new devices but also perform a gap analysis to identify gaps in clinical evidence under the new rules for devices currently on the market, because the clinical evidence for existing devices needs to be updated. For high-risk devices and permanent implants, a summary of clinical evaluation will be publicly available, so convincing clear evidence will need to be provided in layperson's terms.

Subject	Before coming into force	During	After
Chapter VI Clinical evaluation and clinical investigations	Understand new clinical requirements (e.g. new definition of 'clinical data'); define gap between current clinical evaluation of devices and future model according to Article 49 Review and update internal procedures for planning and commissioning clinical investigations	Consider prior review of clinical studies for class III and implantable devices; perform clinical evaluation in accordance with new mode Check transition timescales and requirements for when this needs to be undertaken to meet the requirements of the new certificate	
			Continued

Subject	Before coming into force	During	After
	Define devices that are clinically significantly similar in clinical performance and safety on the market and make gap assessment for substantiating equivalency to amend clinical evaluation for each device currently on the market (Article 49)	Implement plan for amending technical file changes and certification of changes by notified body Ensure access to equivalency relevant data of other manufacturers by entering into agreement with other manufacturer (Article 49) Plan to commission own clinical trials if equivalence data will not be acceptable in future	In case of a clinical evaluation relying on equivalency data, the manufacturer doing so must enter into an agreement with the manufacturer of the device referred to, allowing the notified body full access to the technical documentation on an on-going basis (Article 49)
	Understand new clinical investigation regime (Articles 50–60)	Prepare for any scrutiny reviews and for scientific pre-meetings with European expert committee	
		Understand and implement new application and modification mechanism for clinical investigations as well as recording/reporting requirements	Use new application and modification mechanism for clinical trials as well as recording/reporting requirements
	Prepare for mandatory PMCF	Implement procedures for PMCF	
ANNEX XIII CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP	Perform gap analysis of current clinical evaluation method and outcomes per devices against new requirements	Implement new requirements for clinical evaluation Generate clinical evidence to meet new requirements Apply new requirements optionally	Generate clinical evidence to new requirements; apply new requirements
	Perform gap analysis of current PMCF method and outcomes per device against new requirements	Implement new requirements for PMCF, generate clinical evidence to meet new requirements Apply new requirements optionally	Generate PMCF to new requirements; apply new requirements
ANNEX XIV CLINICAL INVESTIGATIONS	Perform gap analysis to determine new clinical investigation requirements and impact on existing clinical investigation plans	Apply new clinical investigation criteria	Apply new clinical investigation criteria

Chapter VII – Post-market surveillance, vigilance and market surveillance

Post-market surveillance (PMS) and vigilance requirements will be revisited. Manufacturers will need to amend their current PMS and vigilance procedures. PMS will need to be brought into a continuous evaluation and improvement loop, linking to continuous reviews of risk management and to an annual update of a public summary of safety and performance, as well as clinical evaluation.

Manufacturers will need to amend their current post-market surveillance and vigilance procedures

Subject	Before coming into force	During	After
Chapter VII Post-market surveillance, vigilance and market surveillance	Understand new PMS system required and perform gap analysis against current system used	Design and implement new PMS plan (plan for consequences of ongoing PMCF and PMS obligations as long as devices are still in installed base) Gather PMS clinical data as early as possible on any product currently based on equivalence	Use new PMS system (deal with consequences of ongoing PMCF and PMS obligations as long as devices are still in installed base)
			Prepare periodic safety update to notified body reporting according to prescribed model
	Understand new vigilance reporting requirements, including new trend reporting requirements	Implement new vigilance reporting requirements Implement trend reporting system (Article 61a)	Apply new vigilance reporting requirements Apply new trend reporting requirements

Chapter VIII – Cooperation between member states, Medical Device Coordination Group, EU reference laboratories, expert panels and device registers

The new regulation will put in place improved and more centralized governance structures, which means that the member states will cooperate closer in cross-border matters on borderline devices and enforcement. On top of that, groups of experts will write a growing number of guidance documents and minimum requirements. These guidance documents will take the form of CS, and will focus heavily on expectations for clinical data sets and minimum patient outcomes for specific categories of devices. The first of such documents – on trans-catheter heart valves TAVI – is currently being worked on and will set the scene.

Subject	Before coming into force	During	After
Chapter VIII Cooperation between member states, Medical Device Coordination Group, EU reference laboratories, expert panels and device registers		Investigate early which scientific discussions might help smooth market introduction at a later stage	

Chapter IX – Confidentiality, data protection, funding, penalties

The regulation makes provision for a penalties regime as well as for possibilities for member states to institute market-funded market surveillance based on the regulation. Companies will need to prepare for additional local costs of market surveillance, as well as for member states changing enforcement policies to align with the regulation.

Subject	Before coming into force	During	After
Chapter IX Confidentiality, data protection, funding, penalties	Prepare for new penalties regime under MDR		

Chapter X – Final provisions

The transitional regime for the MDR is currently still not fixed. Consequently, manufacturers cannot be sure yet what the transitional regime will look like in terms of (1) transitional period duration and (2) when CE certificates issued under the current Directives will expire. There appears to be political momentum in the Council and Commission camps to extend the transitional period by allowing certificates to be issued under the current rules at the end of the transitional period (three years) for a longer duration (four years), but it is not certain if this will be accepted by the European Parliament.

The Regulation will permit 'sunshine compliance', i.e. the possibility to comply with the new rules during the transitional period. Manufacturers will need to carefully review the new rules for each device group and define a strategy to comply with the new requirements. There are many factors to consider, such as when the first notified bodies will be informed under the new rules (likely in the second half of the first year of the transitional period) and the availability of notified body resources to assess and certify the devices concerned.

Under all circumstances, manufacturers will need to invest resources in developing a transition plan for their devices currently on the market, since all such medical devices will need to be (re)certified under the new rules, as no grandfathering has been foreseen in the new EU regulations. This means that none of the devices on the European market will be able to continue under the current rules and all devices must be transitioned into the new system; in most cases technical files will need to be revisited, additional clinical evidence must be generated and declarations of conformity must be amended.

Subject	Before coming into force	During	After
Chapter X Final provisions	Understand transitional regime for devices placed on the market during transitional period	Apply transitional regime for devices placed on the market during 3-year transitional period Determine and add to transition plan which products might be outfaced and that consequently could stay for a further period on an MDD or Active Implantable Medical Devices (AIMD) certificate after the transition period	Recertify devices on certificates issued during the transitional period under the old rules (up to 2–5 years after end of transitional period)

Conclusion

In conclusion, the MDR will bring about very significant changes that will affect all devices from manufacturers currently on the European market. Not only will the administrative burden increase substantially as a result of registration requirements and UDI, but manufacturers will also have to revisit all technical files and the quality system for all their devices currently on the market. They may need to generate additional clinical evidence for devices currently on the market in order to be able to transition them to the new regime implemented by the MDR.

Consequently, manufacturers must take a pro-active approach to the new regulation, plan for the transition of existing devices in a timely and detailed way, and allocate resources for this effort. Since their notified body may not be around anymore to re-certify devices on the market or new devices, manufacturers must plan for a possible transition from their current notified body.

For the new devices manufacturers must decide whether they want to comply with the new rules already during the transitional period or when that period expires. Again, a pro-active approach is needed as the MDR will require more clinical evidence, especially for higher risk devices, which will take time to generate.

Appendix A

Checklist of manufacturer actions before, during and after transitional period

Subject	Before coming into force	During	After
Chapter I Definitions	Check if cosmetic implants or other products are on Annex XV list	Look out for Common Specifications (CS) for Annex XV devices and implement them	
	Check if devices fall in enlarged scope of 'accessory'	Obtain CE mark for accessory under new regime	Obtain CE mark for accessory under new regime
	Check if custom device is still custom device under new definition	Obtain CE mark if changed to regular medical device	
	Products specifically intended for the cleaning, disinfection or sterilization of medical devices and devices for the purpose of control or support of conception will be considered medical devices		
	Make gap assessment for information required for CE marking of devices concerned	Develop and implement transition strategy for devices concerned into CE marking, generate information needed for CE marking	Obtain CE mark for devices concerned under new regime
	Standalone software is no longer classified as active medical device: revisit classification of software currently on the market as medical device and make gap assessment for additional technical file requirements for software classified in higher risk class	Amend technical files for software in accordance with requirements for higher risk class, have software CE marked by notified body if class IIa or higher	Apply classification rules for new software
Chapter II Making available of devices, obligations of economic operators, reprocessing, CE marking, free movement	Assess potential effect of reprocessing and home brews under new hospital produced (so called 'home brew') devices rules on company business model	Monitor compliance of hospitals with reprocessing and home brews under new hospital produced devices rules	Monitor compliance of hospitals with reprocessing and home brews under new hospital produced brew devices rules (task of national authorities)
		Manufacturers must establish, execute, maintain and document a system for risk management as described in Section 1a in Annex I	

Continued

Subject	Before coming into force	During	After
	Article 5: assess medical devices provided as service via internet	CE mark device as service under new regime	
	Assess own brand labelling consequences of the requirements that a full technical file must be present at each manufacturer (Article 8 (4))	Change business and certification setup into virtual contract manufacturing, or get all required contracts to access key documentation from OEM in place	
	Review new manufacturer responsibilities and make gap assessment against QMS	Amend and implement amended QMS Apply QMS optionally to devices placed on the market in transitional period	Apply amended QMS
	Make gap assessment against new recall requirements (Article 8 (8)) Amend procedures and distribution agreements – adopt new requirement '[8a. Manufacturers shall have a system for reporting of incidents and field safety corrective actions as described in Article 61]'		
	Make gap assessment against new QMS criteria in Article 8 (5); amend procedures	Implement amended QMS; consider revising directly into new ISO 13485 at the same time	
	Article 8 (13): mandatory insurance for product liability, monitor developments	Purchase and maintain relevant insurance	Maintain relevant insurance
	New AR requirements Articles 9–10 – amend AR agreement and procedures – expect AR renegotiations or AR to cease activity if liability requirements are adopted	Ensure continued access to AR services when relevant	
	Review autonomous general obligations of importers and distributors (Articles 11–12), e.g. verify compliance of the device, inform competent authority of non-compliance of the device and implement corrective action and amend contracts accordingly	Implement SOPs, amend agreements in supply chain	

Continued

Subject	Before coming into force	During	After
	Article 13: select and mandate candidate for person responsible for regulatory compliance	Make and keep available in the organization, a person responsible for regulatory compliance; ensure training and where appropriate take out personal liability insurance	Keep available in the organization a person responsible for regulatory compliance
	Prepare for new relabelling/ repackaging regime (Article 14), draft SOP for new regime	Implement and apply SOP	Apply SOP
	Article 15: new regime for reprocessing – design traceability that can show if an incoming complaint is about a new or reprocessed single-use device	Determine what member states will allow reprocessing Implement traceability that can show if an incoming complaint is about a new or reprocessed single-use device Ensure any reprocessing is resulting in patient safety to stay on level of first time use	Ensure any reprocessing is resulting in patient safety to stay on level of first time use Continue to monitor changed allowance per country
	Implant card (Article 16 and implementing acts)	Define system of implant cards, or alternative allowed systems	
	DoC model (Article 17, Annex III) – check for gaps against current model used	Amend existing DoC upon transfer per product (group) into the new requirements aligned with transfer plan agreed with notified body	Use MDR provided DoC model
	Article 21: parts manufacturers to ensure that the part does not adversely affect the safety and performance of the device	Parts manufacturers must generate supporting evidence for this Supporting evidence shall be kept available to the competent authorities of the member states	Parts manufacturers to generate supporting evidence for each new part placed on the market and to be kept available to the competent authorities of the member states
Chapter III Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, EUDAMED	UDI (Article 23 (1)): distributors and importers shall co-operate with the manufacturer or authorized representative to achieve an appropriate level of traceability of devices – implement changes to distribution agreements	Implement changes to distribution agreements and SOPs	

Continued

Subject	Before coming into force	During	After
	Article 23 (2): for devices, other than custom-made or investigational devices, economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 8(4): (a) any economic operator to whom they have supplied a device; (b) any economic operator who has supplied them with a device; (c) any health institution or healthcare professional to whom they have supplied a device – implement and improve traceability	Put traceability systems in place in supply chain, where possible based on UDI	
	Article 24 (3): assign UDI to device and higher levels of packaging and (24 (4)) place that on the label and higher levels of packaging and (24a–c and (5)) keep UDI administration for reporting and tech file	Choose type of UDI system to be applied, in line with global requirements towards UDI	
		If possible, manufacturers may (Article 24b) apply new process for registration of devices prior to placing on the market	Article 24b: apply new process for registration of devices prior to placing on the market
		When implemented, companies may apply process for registration of manufacturers, and ARs and importers, to obtain a single registration number to identify them for the purposes of UDI and traceability	Article 25a: apply process for registration of manufacturers, authorized representatives and importers, single registration number
	Article 26: identify information that must be reflected in summary of safety and performance for each device and conceive plan for generating summaries for each class III and implantable device	Article 26: execute plan for producing summaries for each device Make available summaries for implantable and class III certified under MDR	Article 26: draw up and make available summary of safety and clinical performance for class III and implantable devices, other than custom-made or investigational devices
		If available, Article 27: enter data into EUDAMED	Article 27: enter data into EUDAMED

Continued

Subject	Before coming into force	During	After
Chapter IV Notified bodies	Make assessment of notified body's potential to be re-notified under new system	Re-notification to be timely; with long delays in re-notification consider alternative plans	
	Agree re-assessment plan with current notified body or agree transition plan to new notified body if necessary		
		Article 36: analyse and implement new transition procedures for dealing with consequences of changes in designation and cessation of notified bodies	
Chapter V Classification and conformity assessment	Perform a gap analysis of all devices on the market against new classification rules and make transition plan if classification necessitates new conformity assessment, class II implants may be subject to additional clinical scrutiny procedure (Article 42 (2a))	Implement transition plan for reclassified devices	
		Apply new conformity assessment procedures to devices already on market and optionally to new devices to be placed on the market Select devices which have documentation to support the new essential principles	Apply new conformity assessment procedures to devices
	Article 42: make QMS gap analysis against the new rules	Apply new QMS optionally in case of new devices to be placed on the market	Apply new QMS in case of new devices to be placed on the market
			Article 46: conclude tripartite transition agreement with outgoing and incoming notified body in case of voluntary change of notified body
	Do gap assessment for consequences of new substance-based devices, rule 21 (class IIb default, class IIa in case on skin, class III if systematically absorbed)	Work on reclassification where appropriate	Apply new classification rule 21

Continued

Subject	Before coming into force	During	After
	Do gap assessment for consequences of spinal implants, reclassification (spinal disc replacement implants and implantable devices that come into contact with the spinal column, in which case they are in class III with the exception of components such as screws, wedges, plates and instruments, rule 8)	Work on reclassification where appropriate	Apply new classification rule 8
		Article 48: uniform certificates of free sale will be issued by member states	Article 48: uniform certificates of free sale will be issued by member states
Chapter VI Clinical evaluation and clinical investigations	Understand new clinical requirements (e.g. new definition of 'clinical data'); define gap between current clinical evaluation of devices and future model according to Article 49 Review and update internal procedures for planning and commissioning clinical investigations	Consider prior review of clinical studies for class III and implantable devices; perform clinical evaluation in accordance with new mode Check transition timescales and requirements for when this needs to be undertaken to meet the requirements of the new certificate	
	Define devices that are clinically significantly similar in clinical performance and safety on the market and make gap assessment for substantiating equivalency to amend clinical evaluation for each device currently on the market (Article 49)	Implement plan for amending technical file changes and certification of changes by notified body Ensure access to equivalency relevant data of other manufacturers by entering into agreement with other manufacturer (Article 49) Plan to commission own clinical trials if equivalence data will not be acceptable in future	In case of a clinical evaluation relying on equivalency data, the manufacturer doing so must enter into an agreement with the manufacturer of the device referred to, allowing the notified body full access to the technical documentation on an on-going basis (Article 49)
	Understand new clinical investigation regime (Articles 50–60)	Prepare for any scrutiny reviews and for scientific pre-meetings with European expert committee	
		Understand and implement new application and modification mechanism for clinical investigations as well as recording/reporting requirements	Use new application and modification mechanism for clinical trials as well as recording/reporting requirements
	Prepare for mandatory PMCF	Implement procedures for PMCF	

Continued

Subject	Before coming into force	During	After
Chapter VII Post-market surveillance, vigilance and market surveillance	Understand new PMS system required and perform gap analysis against current system used	Design and implement new PMS plan (plan for consequences of ongoing PMCF and PMS obligations as long as devices are still in installed base) Gather PMS clinical data as early as possible on any product currently based on equivalence	Use new PMS system (deal with consequences of ongoing PMCF and PMS obligations as long as devices are still in installed base)
			Prepare periodic safety update to notified body reporting according to prescribed model
	Understand new vigilance reporting requirements, including new trend reporting requirements	Implement new vigilance reporting requirements Implement trend reporting system (Article 61a)	Apply new vigilance reporting requirements Apply new trend reporting requirements
Chapter VIII Cooperation between member states, Medical Device Coordination Group, EU reference laboratories, expert panels and device registers		Investigate which scientific discussions in early phase might help smooth market introduction at a later stage	
Chapter IX Confidentiality, data protection, funding, penalties	Prepare for new penalties regime under MDR		
Chapter X Final provisions	Understand transitional regime for devices placed on the market during transitional period	Apply transitional regime for devices placed on the market during 3-year transitional period Determine and add to transition plan which products might be outfaced and that consequently could stay for a further period on an MDD or AIMD certificate after the transition period	Recertify devices on certificates issued during the transitional period under the old rules (up to 2–5 years after end of transitional period)

MDR Annexes

Subject	Before coming into force	During	After
ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS	Gap analysis of consequences of changed 'essential requirements' for recertification of existing devices (rule 21, Annex XV, new software requirements) Gap analysis of requirements for new devices	Gap analysis of consequences of changed 'essential requirements' for recertification of existing devices (rule 21, Annex XV) Gap analysis of requirements for new devices	
ANNEX II TECHNICAL DOCUMENTATION	Gap analysis of existing technical files against new technical file requirements	Amend existing technical files against new technical file requirements and recertification based on amended technical file	Use new technical file requirements
ANNEX III EU DECLARATION OF CONFORMITY	Gap analysis of existing DOC against new DOC requirements	Amend existing DOC against new DOC requirements and recertification based on amended technical file	Use new DOC requirements
ANNEX IV CE MARKING OF CONFORMITY	No changes	No changes	No changes
ANNEX V INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS	Perform gap analysis of information for EUDAMED database and for UDI purposes Prepare for implementation for EU-UDI	Implement EU-UDI for existing and new devices and register them in EUDAMED database	Use EU-UDI and register new devices in EUDAMED
ANNEX VI MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES	Contact notified body to discuss if it can meet the new requirements and prepare for transition if needed	Notified body may or may not be re-notified under new criteria; move to new notified body in case notified body not re-notified or has scope restricted as to not support devices concerned any longer	
ANNEX VII CLASSIFICATION CRITERIA	Analyse devices under new classification criteria to determine if they will be reclassified	Recertification of existing devices under new classification rules	Apply new classification rules to new devices
ANNEX VIII CONFORMITY ASSESSMENT BASED ON FULL A QUALITY MANAGEMENT SYSTEM ASSURANCE AND DESIGN EXAMINATION	Perform gap analysis between current full QMS and new full QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS	Apply new QMS

Continued

Subject	Before coming into force	During	After
ANNEX IX CONFORMITY ASSESSEMENT BASED ON TYPE EXAMINATION	Perform gap analysis between current type examination QMS and new type examination QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS	Apply new QMS
ANNEX X CONFORMITY ASSESSEMENT BASED ON PRODUCT CONFORMITY VERIFICATION	Perform gap analysis between current product verification QMS and new product verification QMS requirements, improve QMS where necessary	Recertification of existing devices under new QMS	Apply new QMS
ANNEX XI CONFORMITY ASSESSMENT PROCEDURE FOR CUSTOM-MADE DEVICES		Apply procedure for custom-made devices optionally to devices in scope	Apply procedure for custom-made devices in scope
ANNEX XII MINIMUM CONTENT OF CERTIFICATES ISSUED BY A NOTIFIED BODY	No action required by manufacturer	No action required by manufacturer	No action required by manufacturer
ANNEX XIII CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP	Perform gap analysis of current clinical evaluation method and outcomes per devices against new requirements	Implement new requirements for clinical evaluation Generate clinical evidence to meet new requirements Apply new requirements optionally	Generate clinical evidence to new requirements; apply new requirements
	Perform gap analysis of current PMCF method and outcomes per device against new requirements	Implement new requirements for PMCF, generate clinical evidence to meet new requirements Apply new requirements optionally	Generate PMCF to new requirements; apply new requirements
ANNEX XIV CLINICAL INVESTIGATIONS	Perform gap analysis to determine new clinical investigation requirements and impact on existing clinical investigation plans	Apply new clinical investigation criteria	Apply new clinical investigation criteria
ANNEX XV LIST OF GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE	Identify Annex XV candidate devices in company's portfolio Watch for CS becoming available for devices concerned Start building up technical documentation and if necessary quality management system (QMS)	CE mark Annex XV devices using CS	

BSI is grateful for the help of the following people in the development of the white paper series.

Authors

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Gert has 21 years of experience in life sciences (devices and pharma), in university, industry as well as in four notified bodies. His last notified body roles were Head of Regulatory and Clinical Affairs of BSI Medtech and Head of Notified Body at BSI-Germany (NB0535). He has been President of the Notified Body association TEAM-NB, and Vice Chair of the Medical Notified Body forum NB-Med in Brussels. In these roles for many years, he represented notified bodies in a.o. the Clinical Investigation and Evaluation Group (CIE), Medical Device Expert Group (MDEG) and the MDEG workgroups on animal tissue, on MRAs, e-labeling, EUDAMED and on IVDs, as well as the IMDRF workgroup on Regulated Product Submissions and Table of Content. In addition, he served as NB-representative at EMA/CAT and Medical Device Collaboration group. He is a founding board member of the Dutch RAPS chapter.

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Erik is a lawyer specializing in EU legal issues relating to medical devices. He has wide experience in life sciences legislation and regulatory issues, at both the EU and Dutch level. Vollebregt was trained as an intellectual property and competition lawyer. He has gained experience in contentious matters, commercial contracts, and transactional work at the Directorate-General for Competition of the European Commission. He is a prolific writer and publishes in life sciences legal and regulatory journals on a wide variety of subjects. Vollebregt authored several medical technology chapters of RAPS Fundamentals of EU Regulatory Affairs and is writing a chapter on software for Fundamentals of International Regulatory Affairs.

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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/ISO 80601-2-58) and a committee member of US TAG for TC62, SC62A and 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*.

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Sabina joined Philips Healthcare in 2011 after an extensive career as pharmaceutical and medical device regulator in the Dutch Government, in which she has represented the Netherlands in several EU and international working groups. In her present role, she is also acting as Vice-Chair EU Regulatory Affairs Focus Groups of COCIR (European trade association for the Radiological, Electromedical and Healthcare IT Industry), Chair of Netherlands Chapter of RAPS (Regulatory Affairs Professional Society) and Member of the Content Committee for Europe and Faculty Chair for medical devices of DIA (Drug Information Association).

Advisory Panel

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Jane holds a BSc in Chemistry and an MBA from Durham university. She has over 10 years' experience in the medical device industry, having previously worked for Coloplast in their ostomy and continence business. Jane's experience includes working within the pharmaceutical, chemical and telecoms industries for Glaxo Wellcome, ICI and Ericsson, allowing her to bring depth of knowledge from across many industries and technologies. Her current role in BSI allows her to work with technical reviewers across all disciplines ensuring that all BSI communications are accurate and relevant. She is a member of the European Medical Writers Association.

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Terry has been employed in the medical equipment industry all his working life. Having qualified as a mechanical engineer he then, over the following 40+ years, experienced both sides of the medical industry, the technical side and the commercial side, with various companies that manufactured everything from capital medical equipment to consumable medical devices.

Since 1995, he has been a self-employed consultant specializing in all matters related to standards including advising companies on compliance with the European Medical Devices Directive and US FDA directives. He represents the members of the British Anaesthetic and Respiratory Manufacturers Association (BAREMA) at BSI meetings. BAREMA comprises manufacturers from all parts of the Anaesthetic and Respiratory industry. He also represents several individual companies at ISO and CEN meetings. Terry is on several national, European and international standards committees, the following as Chairman: CEN/TC/215, CH/121, CH/121/1, CH/121/5, CH/121/9 and CH/210/5.

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SMTL, based in Bridgend in South Wales, is funded by the Welsh Government to test medical devices for the Welsh NHS and to provide technical advice on medical devices. Pete 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 NonLuer 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

Forthcoming white papers

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

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

Sterilization Practices in Response to Device Innovation (working title)

Getting your Clinical Data: Away from Clinical Equivalence in Europe (working title)

The Future of Standards in Europe – Harmonization and other Recognitions of Standards (working title)

Cyber Security for Medical Devices (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:
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