Medical Devices Regulation (MDR)
Regulation (EU) 2017/745

Version 2, May 2017

Frequently asked questions

This FAQ document aims to answer some key questions on the new MDR and the anticipated impact on manufacturer resources. Questions are grouped by key theme. For more information, please see our MDR transition webpage. **Note:** *Article and Annex references are correct at the time of publication. Any changes will result in an updated version of this document*

Transition period

What is the transition period for the MDR?

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

The MDR, replaces the Medical Devices Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC), and has a transition period of three years. Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new requirements. Article 120 of the Regulation states a number of transitional provisions, and should be referred to for more detail.

Will the new requirements be enforced retrospectively?

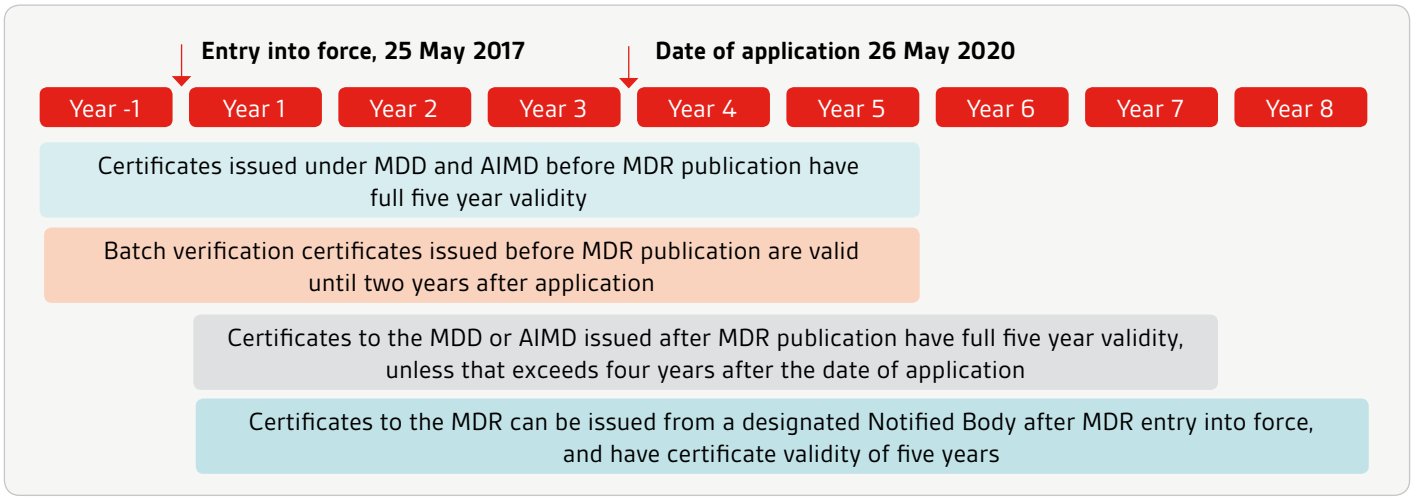
No, the new requirements will be applied to all devices only when they are to be certified under MDR. After the transition period, devices not conforming to the MDR will need to be removed from the market.

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

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

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

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.*

Notified Body activity

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

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

When will BSI begin conformity assessment against the new Regulation?

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

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

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

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

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

Impact of the MDR on Quality Management Systems (QMS)

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

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

Note: *ISO 13485:2016 was published in March 2016, with a transition period of three years. We are awaiting the harmonization of this standard to allow the presumption of conformity to the current Directives. It is also important to consider whether ISO 13485:2016 is harmonized to the Regulation in the future.*

How will the new MDR impact contract manufacturers?

If a contract manufacturer intends to take legal manufacturer responsibility for the devices that they provide to market, they must comply with the Regulation in its entirety.

If a contract manufacturer does not take legal manufacturer responsibility, the only implication is that they may be subject to audits on behalf of the legal manufacturers they provide services to. This includes unannounced audits.

Continued >>

Version 2 May 2017

Medical Devices Regulation scope

What devices are covered by the MDR?

All devices covered by the previous Medical Devices Directive (MDD, 93/42/EEC) or the Active Implantable Medical Devices Directive (AIMD, 90/385/EEC) are included in the MDR. The scope has also been extended to include a number of additional devices. See Annex XVI of the MDR for more information.

Are there any changes to device classification?

There are a few changes to the classification rules under the MDR, which has a broader scope than the Directives it supersedes. Please refer to Annex VIII of the MDR for more detail.

Technical documentation

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

Class IIb implantable devices will require product specific certificates - see Annex IX or Annex X of the MDR for more information. These certificates will have UDI for devices covered. Changes to these certificates will require review by the Notified Body prior to them issuing a certificate that covers the devices to be placed on the market in the EU.

Is the Technical Documentation assessment for Class IIb implantable devices based on a representative sample of the generic device group?

The language in the MDR suggests that Class IIb implantable devices will need a detailed Technical Documentation review analogous to a Class III device under the current MDD. Hence sampling may not be possible.

Are five year renewals for Class III devices subjected to Commission review, or does this just apply to the original application?

Five year renewals are not subject to Commission review assuming there were no substantial changes made to the device which may require a Commission review.

Have the requirements for Technical Documentation for Class IIb products that deliver medicines increased?

The language in the Regulation suggests a more robust set of Technical Documentation similar to a Design Dossier under the current MDD/AIMD. Class IIb active devices intended to deliver medicines can also be subject to scrutiny as described in Annex IX or Annex XI of the MDR.

Am I able to self-certify devices under the MDR?

It is possible to self-certify Class I, non-measuring, non-sterile, non-reusable products under the MDR.

What documentation will I need to provide for a Class I reusable device with regards to cleaning?

Along with the cleaning instructions and associated validations, Notified Body assessment will also include other areas such as disinfection, sterilization, maintenance, functional testing. For more information, see Article 52 of the MDR.

Does the requirement for implant cards apply to resorbable implants?

Yes, all implants must have an implant card.

Continued >>

Version 2 May 2017

Clinical requirements

Will I be required to perform testing to ISO 10993 for an equivalent device?

Possibly. It depends on how equivalent the subject and the comparator devices are from a biological perspective. Please also note that the MDR has separate stand-alone safety and performance requirements related to biological safety of the device which may also require compliance with ISO 10993.

Will the Periodic Safety Update Report (PSUR) need to be included in the Clinical Evaluation Report (CER)?

The MDR requires that the Clinical Evaluation is updated periodically based on Post Market Surveillance (PMS) data. However, inclusion of the PSUR in the CER is optional. The PMS data which the PSUR is based on should be used to update the CER.

Do the post-market reporting requirements apply to only Class III implantable products, or to all Class III and also to all implantable products?

BSI's interpretation is inclusive; that it applies to Class III devices and all implantable devices.

Do the Periodic Safety Update Report (PSUR) and Summary of Safety and Performance requirements (SSP) have to be generated by individual device or can they be generated by device family?

This will need to be considered on a case-by-case basis. With regards to SSP, Article 32 indicates that the Device Identifier is included in the SSP. With regards to PSUR, the wording in Article 86 allows PSUR to be prepared per device and where relevant per category or group of devices. If such grouping were to occur, Notified Bodies expect that the rationale behind grouping the devices is clearly documented.

Common Specification (CS)

What is a Common Specification?

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

When will Common Specifications be published?

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

Requirements for device-drug combinations

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

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

Requirements for devices containing tissue of animal origin

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

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

Continued >>

Version 2 May 2017

Unique Device Identifiers (UDI)

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

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

Will there be a database where UDIs are logged?

Yes, the European database will be EUDAMED.

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

In the case of individually packaged items, where each unit of use is individually packaged, a UDI is required on the packaging on each item.

In the case of items packaged together in one container where the unit of use is not individually packaged (e.g. a box of surgical gloves), only the outer packaging requires the UDI, not each individual item.

For more information, please refer to the most recent wording of Article 27 and Annex VI.

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

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

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

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

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

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

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

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

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

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

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

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

Continued >>

Version 2 May 2017

How can BSI support me through the transition?

BSI has a range of materials designed to provide information about the new requirements related to the Medical Devices Regulation, and the transition period.

How can I keep up to date with the changes in industry?

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

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

Where can I find more information to expand my knowledge?

BSI offers a wide range of free webinars and white papers, to keep you informed on the current thinking and latest changes in the regulatory space. Take advantage of our expertise and learn more about key topics including legislation, risk and regulatory changes.

BSI's suite of training courses can provide more support, from introductory courses through to more specialised programmes aimed at those with regulatory experience. Call us for more information: **0345 086 9000**.

BSI Group America Inc.
12950 Worldgate Drive,
Suite 800,
Herndon,
VA 20170
USA

T: +1 800 862 4977/703 437 9000
F: +1 703 437 9001
E: us.medicaldevices@bsigroup.com

BSI Group - EMEA
Kitemark Court,
Davy Avenue,
Knowlhill,
Milton Keynes MK5 8PP
United Kingdom

T: +44 345 080 9000
F: +44 1908 814920
E: eu.medicaldevices@bsigroup.com

BSI Group Asia Pac
BSI Group - Hong Kong
23rd Floor, Cambridge House
TaiKoo Place,
979 King's Road,
Island East, Hong Kong

T: +852 3149 3320
F: +852 2743 8727
E: hk@bsigroup.com

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