Medical Devices Regulation (MDR) Readiness Review

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<tr>
<th>Company Name</th>
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How ready are you for the Medical Devices Regulation?

The MDR, which replaces the Medical Devices Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC), 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. BSI is committed to ensuring a smooth transition for all clients wishing to certify to the MDR.

This document allows you to detail how you intend to meet the additional requirements of the new Regulation, so should be used in conjunction with Regulation (EU) 2017/745. It is NOT an exhaustive checklist, but contains summary statements of the significant changes.

Completion of this form is not mandatory and does not need to form part of the transition process, but can help with your internal preparation and be a useful tool for planning your transition strategy. Use the boxes below to list procedures, records and examples that address the additional requirements. This can be used as a gap analysis tool or as an aide memoire during your transition.

Your BSI Team is here to support you on your journey, so please talk to us about your plans early on in your preparation. Further information can be found BSI MDR revision page [www.bsigroup.com/MDRRevision](http://www.bsigroup.com/MDRRevision).

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EU Directives lay down certain end results that must be achieved in every Member State. National authorities have to adapt their laws to meet these goals, but are free to decide how to do so.

Regulations are the most direct form of EU law - as soon as they are passed, they have binding legal force throughout every Member State, on a par with national laws. National governments do not have to take action themselves to implement EU regulations.
Scope

The scope of the Regulation is significantly increased compared to the Directives, and you will need to check if you are affected by any of the following scope changes.

Products newly included:
- Products manufactured utilizing derivatives of tissues or cells of human origin that are non-viable or are rendered non-viable (Article 1)
- ‘Prediction’ and ‘Prognosis’ of disease have been added to the definition of a medical device (Article 2)
- ‘...specifically intended for the cleaning, disinfecting or sterilisation of devices ...’ has been added to the definition of a medical device (Article 2)
- ‘...specifically and directly assist the medical functionality of the device ...’ has been added to the definition of accessory (Article 2)

You will need to document information on any products that fall within the new Regulation, which were previously not covered by the Directive:

Products for which the requirements are addressed in a Common Specification (CS):
- Products that have only an aesthetic or another non-medical purpose (contact lenses, invasive devices modifying anatomy or fixation of body parts, substances filling facial or mucous membranes, equipment to reduce, remove or destroy adipose tissue, high intensity electromagnetic radiation emitting devices, intense pulsed light equipment, equipment for brain stimulation) (Article 1, Annex XVI).
- Products to be reprocessed (Article 2)

CSs are mandatory for Annex XVI devices and reprocessing but will also exist for other devices/aspects.
- BSI believe there will be other products for which Common Specifications will be issued, so the above list is not intended to be exhaustive. You should monitor the development of CS’s for your product areas

You will need to document information on:
- Processes to check for publication of and/or changes in Common Specifications, Implementing Acts and Delegated Acts
- Processes to check for or identify Member States where reprocessing is permitted, if applicable
Classification (Article 51 & Annex VIII)

Products that may have changed classification:
- Rule 3 – IVF media and organ/tissue/cell storage solutions
- Rule 4 – Non-invasive devices in contact with injured mucous membranes
- Rules 6, 7 – Surgically invasive devices intended specifically for direct contact with heart or central circulatory system are now class III similar to devices in contact with central nervous system
- Rule 8 – Active Implantable Medical Devices (AIMD) and their accessories are now Class III, under the MDR and are NOT covered in a separate Regulation
- Rule 8 – Total and partial joint replacement implants are now class III with the exception of ancillary components such as screws, wedges, plates and instruments
- Rule 8 – Spinal disc replacement implants and implantable devices that come into contact with the spinal column are now Class III with the exception of components such as screws, wedges, plates and instruments
- Rule 8 – Surgical mesh devices are now Class III
- Rule 9 – Active devices which control or monitor or directly influence performance of devices intended to emit ionizing radiation for therapeutic purposes are now Class IIb
- Rule 9 – Active devices which control or monitor or directly influence performance of Active Implantable Medical Devices are now Class III
- Rule 10 - Active devices intended for diagnosis in clinical situations where the patient is in immediate danger are class IIb
- Rule 11 – Software
- Rule 14 – Devices with medicinal substances regardless of if the medicinal substance is ‘liable to act’ are class III
- Rule 16 – All disinfectants or sterilizers intended for disinfecting invasive devices, as the end point of processing, are Class IIb. Other devices intended specifically to be used for disinfecting or sterilizing medical devices are classified as class IIa
- Rule 18 – Devices utilizing non-viable human tissues, cells or derivatives are in Class III
- Rule 19 – Devices incorporating nanomaterials
- Rule 20 – Invasive devices with respect to body orifices, intended to administer medicinal products by inhalation
- Rule 21 – Invasive devices with respect to body orifices or applied on the skin that are absorbed or locally dispersed
- Rule 22 – Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determines patient management are now Class III

There is no need for Declarations of Conformity to reference 2003/12/EC or 2005/50/EC as these have been repealed

The list above is a top level summary of products that may have changed classification. Manufacturers are recommended to evaluate Annex VIII fully prior to completing the section below. You will need to document information on any devices that may have changed classification:

<table>
<thead>
<tr>
<th>Device</th>
<th>MDD/AIMD Classification</th>
<th>MDR Classification</th>
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<td>X</td>
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Routes of Conformity (Article 52)

Products that may have changed route of conformity:
- ‘...devices which are mass-produced by means of industrial manufacturing processes shall not be considered to be custom-made devices’ (Article 2)
- Custom made Class III implantable devices (Article 52, Clause 8)
- ‘reusable surgical instrumentation’ (Article 52, Clause 7)
- Class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors – require Technical Documentation certificates (Article 52, Clause 4)
- Class III implantable devices and active Class IIb devices intended to administer or remove medicines – require Scrutiny (Annex IX, Section 5 / Annex X, Section 6)
- Class III devices under rule 21 require consultation with a national Competent Authority or EMA

Please note that the Regulation does not have an equivalent to the Directive’s Final Inspection & Testing conformity route (93/42/EEC Annex VI)

Although the Regulation indicates there are four classes of device, the routes of conformity distinguish between nine different groups of devices.

You will need to gather information on:
- Systems and Procedure Packs (Article 22) – sterilized per manufacturer’s instructions
- Parts and Components (Article 23) – items intended to replace parts or components that significantly change the performance, safety characteristics or intended purpose of a device
- Any custom made Class III implantable devices
- Any Class I reusable surgical instruments
- Any Class IIb implantable devices
- Any Class IIb active devices intended to administer or remove medicinal substances
- Any Class III implantable devices
- Any Class III device under rule 21
- Any device containing human cells/tissues or their derivatives

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<thead>
<tr>
<th>Device</th>
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<tbody>
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<td>X</td>
<td>X</td>
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Quality Management System

QMS Requirements to be assessed for ALL EXISTING CE Certifications from 26 May 2020

This includes:
- New requirements Vs MedDev 2.12.1 (Vigilance Reporting) i.e. maximum duration to report 15 days
- New requirements Vs MedDev 2.12-2 (Post Market Clinical Follow-up) i.e. increased frequency of updates
- Process/Procedure for communication with Commission/Member States to obtain SRN
- Registration of Economic Operators including Single Registration Number (Article 31)
- Systems for Market Surveillance (activities described in Article 93)
- Systems for Serious Incident, Field Safety Corrective Action (Article 87) and Trend Reports (Article 88)
- Systems for PMS Plan and Report (Article 84, Article 85)
- Systems for Periodic Safety Update Report (Article 86)

Additional QMS Requirements for MDR Applications
You will need to document information on:
- All systems for any reclassified devices or devices new to the scope of certification (see previous sections)
- Economic Operators Registration (Article 30) and Single Registration Number (SRN) (Article 31)
- The new role of Person Responsible for Regulatory Compliance (Article 15)
- Agreement with EU Authorised Representative i.e. written mandate (Article 11), SRN (Article 11), and including Person Responsible for Regulatory Compliance (Article 15), QMS (Article 8)
- Importers i.e. SRN (Article 31), QMS (Article 13)
- Distributors i.e. QMS (Article 14)
- Strategy for Regulatory Compliance (Article 10) Unique Device Identification and Registration (Article 27, 29)
- Handling communication with regulatory authorities, Notified Bodies, Economic Operators
- Agreement with Importers / Distributors, including evidence of having met Article 13/14 respectively
- A process to identify Safety & Performance Requirements (SPR). See more below

Changes in Activity in BSI Audits
- All QMS audits to carry out or ask to witness physical/laboratory tests in order to check the QMS is working properly
- In the case of Class III devices, tests that are essential for the integrity of the device shall be conducted on approved parts and/or materials
- Unannounced Audits frequency at least once every five years

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Safety and Performance Requirements (SPR).

The SPRs replace the Directive’s Essential Requirements; further details on these changes can be found in the BSI whitepaper: Safety & Performance Requirements in the new Medical Device Regulation.

**New Requirements**

You will need to document information on:

<table>
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<tr>
<th>SPR Number</th>
<th>Comments</th>
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<tbody>
<tr>
<td>2, 3, 4, 5, 8</td>
<td>Gap analysis to EN ISO 14971:2012</td>
</tr>
<tr>
<td>10.4</td>
<td>Substances that are carcinogenic, mutagenic toxic to reproduction, or endocrine disrupting</td>
</tr>
<tr>
<td>10.6</td>
<td>Nanomaterials</td>
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<tr>
<td>12.2</td>
<td>Substances that are absorbed and locally dispersed</td>
</tr>
<tr>
<td>13.1</td>
<td>Tissues, cells or derivatives of human origin</td>
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<tr>
<td>13.3</td>
<td>Utilizing non-viable biological substances</td>
</tr>
<tr>
<td>14.4</td>
<td>Adjustment, calibration and maintenance: safety and effectiveness</td>
</tr>
<tr>
<td>14.5</td>
<td>Interoperability and compatibility reliable and safe</td>
</tr>
<tr>
<td>14.7</td>
<td>Safe disposal after use</td>
</tr>
<tr>
<td>17.2</td>
<td>Information security</td>
</tr>
<tr>
<td>17.3</td>
<td>Specific features of mobile platforms</td>
</tr>
<tr>
<td>17.4</td>
<td>Protection against unauthorized access</td>
</tr>
<tr>
<td>20.4</td>
<td>Errors likely to be made when refitting</td>
</tr>
<tr>
<td>22</td>
<td>Devices intended for use by lay persons</td>
</tr>
<tr>
<td>23</td>
<td>• Presence of human cells, tissues, derivatives • Presence of &gt;0.1% carcinogenic, mutagenic, toxic to reproduction or endocrine disrupting • Reprocessing cycles • Quantity of constituents achieving principal intended action</td>
</tr>
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Clinical Evidence

The Safety and Performance requirements identified in Annex I do not include a specific requirement for Clinical Evidence. Requirements related to clinical data and clinical evaluations are now defined in Article 2, Article 61 and Annex XIV. Many of the requirements of the Regulation are covered by MedDev 2.7.1 Rev 4. Some key issues to consider are:

- **Class III and IIb implants**: clinical investigations are required unless exclusions described in Article 61(4) – (6) apply, and justification in accordance with Article 61(7) is provided
- **Class III implants and IIb devices intended to remove or administer a medicinal substance**: will be subject to an additional EU scrutiny process, including assessment of the clinical evaluation, information for use, and PMCF plan (Article 55)
- **Class III and Class IIb active devices intended to remove or administer a medicinal substance**: Manufacturers may request a consultation from an expert panel prior to its clinical evaluation and / or investigation (Article 61(2))

You will also need to provide:

- A clinical evaluation and development plan (Annex XIV Part A(1a))
- **Summary of Safety and Clinical Performance** (Article 32), with frequency of update described in Article 61
- For **Class III and Class IIb active devices intended to remove or administer a medicinal substance**: evidence related to any expert consultations requested under Article 61(2)

The Regulation applies to clinical investigations conducted in the EU concerning devices/products which fall within the scope.

Clinical investigations are required to be carried out as per Chapter VI and NB reviews of clinical investigation data will check for conformity to Annex XV.

As per Article 120 on-going Clinical Investigations conducted in accordance with 93/42/EEC and 90/385/EEC may continue, however reporting of serious adverse event will need to be in accordance with the Medical Devices Regulation.

You should review the MDR requirements to identify provisions you will need to make to ensure the clinical investigations requirements will be met for your products. Document gaps between EN ISO 14155 and the MDR.

Please note: Reporting of Serious Adverse events must now follow the MDR, and as such you should have provisions in place.
Post Market Surveillance (PMS) Requirements

Post-market surveillance (Article 83), market surveillance, vigilance, registration of economic operators shall be applicable to ALL devices placed on the market or put into service from the date of application, 26th May 2020.

This includes:

- PMS Plan (Article 84)
- PMS Report (Article 85)
- Periodic Safety Update Report (Article 86)
- Serious Incident, Field Safety Corrective Action (Article 87)
- Trend Report (Article 88)
- Market Surveillance (activities described in Article 93)
- Registration of Economic Operators including Single Registration Number (Article 31)

You will need to document information on:

- How to meet the new MDR requirement compared with MedDev 2.12-1 (vigilance guidance) i.e. maximum duration to report 15 days
- How to meet the new MDR requirement compared with MedDev 2.12-2 (post market clinical follow-up) i.e. increased frequency of updates
- Process/Procedure for communication with Commission/Member States to obtain SRN
- Process/Procedure to provide PSUR at frequency described by Article 86
- EU Authorized Representative i.e. written mandate (Article 11), SRN (Article 11), PRRC (Article 15), QMS (Article 8)
- Importers i.e. SRN (Article 31), QMS (Article 13)
- Distributors i.e. QMS (Article 14)
Other Changes

New requirements
You will need to document information on:

- Implant cards (Article 18)
- Declaration of Conformity (Article 19 & Annex IV)
- Unique Device Identification (except for custom made) – obligations start from 1-5 years after date of application (Article 27)
- EUDAMED – obligations start from the date of application (Article 33)

When responses are complete please share with your Scheme Manager as “readiness review”; this will help plan the transition described by Article 120.

Now you have reviewed some of the detailed points on MDR changes, please start to consider what devices from your current product range you may plan to apply for MDR certification for. Your BSI Contacts and Scheme Manager will explore this further with you in future and require more information on this as we move forward.

Please note: This document is a guide to help you to plan 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 document 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.