



Comparison of the articles of the European Medical Devices Directive (93/42/EEC) and the Medical Devices Regulation ((EU) 2017/745)

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CHANGES

Background to changes

The MDR is significantly more comprehensive and detailed compared to the MDD. While the MDD comprises 23 Articles and 12 annexes over 60 pages, the MDR has 123 articles and 17 annexes over 175 pages. This table presents a summary of the provisions of some of the articles of the MDD and MDR together with commentary providing discussion and highlighting the key differences.

The table is an excerpt from the MDR/IVDR Smart Support available in Compliance Navigator.

Topic	Medical Devices Directive (93/42/EEC), as amended	Medical Devices Regulation ((EU) 2017/745)	Comments
Scope - inclusions	<p>Article 1</p> <p>The scope of the MDD covers medical devices and their accessories, including devices that;</p> <ul style="list-style-type: none">✓ incorporate an ancillary medicinal product,✓ are derived from non-viable animal material.	<p>Article 1</p> <p>The scope of the MDR covers medical devices for human use and their accessories including:</p> <ul style="list-style-type: none">✓ Active implantable medical devices (AIMDs),✓ Devices incorporating an ancillary medicinal product, including a medicinal product derived from human blood or human plasma,✓ Devices incorporating ancillary non-viable tissues or cells of human origin or their derivatives,	<p>The scope of the MDR is wider than that of the MDD.</p> <ul style="list-style-type: none">✓ AIMDs that were covered separately in their own Directive have been rolled into the MDR.✓ Ancillary medicinal products combined with a medical device can now include those derived from human blood.✓ Devices incorporating non-viable human tissues or cells are now included.

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		<ul style="list-style-type: none"> ✔ Devices manufactured utilizing tissues or cells of animal origin, or their derivatives, which are non-viable or are rendered non-viable, ✔ Products specifically intended for the cleaning, disinfection or sterilization of devices, ✔ Aesthetic products without an intended medical purpose listed in Annex XVI. 	<ul style="list-style-type: none"> ✔ A change in the definition of medical device now includes products specifically intended for the cleaning, disinfection or sterilization of devices. These were previously covered as accessories to medical devices. The change means that accessories for cleaning, disinfection or sterilization are now in scope of the MDR. ✔ Products with characteristics similar to medical devices but with an aesthetic purpose rather than a medical purpose, such as coloured contact lenses without any visual correction, have been added through a specific list added as Annex XVI to the MDR. <p>For further information, see the BSI whitepaper - Planning for implementation of the European Union Medical Devices Regulations – Are you prepared?</p>
Declaration of conformity and CE-marking	<p>Articles 11 and 17</p> <p>The manufacturer has to draw up a declaration that the device conforms to the MDR and add a CE-mark to the product.</p> <p>The format of the CE mark is given in in Annex XII.</p>	<p>Articles 19 and 20</p> <p>The manufacturer has to draw up a declaration that the device conforms to the MDR and add a CE-mark to the product.</p> <p>The declaration has to be kept up to date and available in the official language or languages required by the Member State(s) in which the device is made available.</p> <p>The information to be included in the declaration of conformity is detailed in Annex IV and the format of the CE mark is given in in Annex V.</p>	<p>The MDR includes detail of the information to be included in the declaration of conformity and adds specific reference to it being kept up-to-date and available in the official language of the Member State(s) in which the device is supplied.</p>

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<p>Post-market surveillance</p>	<p>PMS is mentioned in Annex X of the MDD as being the source of clinical data to update the clinical evaluation and clinical evaluation report. If PMCF is not deemed necessary as part of the PMS plan, this has to be justified and documented.</p> <p>Additionally, the Annexes for conformity assessment require the manufacturer to:</p> <ul style="list-style-type: none"> ✔ institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase; and, ✔ implement appropriate means to apply any necessary corrective action. <p>This is a PMS system</p>	<p>Articles 83 – 86</p> <p>For each device, the manufacturer has to plan, establish, document, implement, maintain and update a post-market surveillance (PMS) system that is proportionate to the risk class and appropriate for the type of device. The PMS system is required to be an integral part of the manufacturer's QMS.</p> <p>The PMS system actively and systematically gathers, records and analyses data on the quality, performance and safety of a device throughout its entire lifetime. Data gathered by the manufacturer's post-market surveillance is used:</p> <ul style="list-style-type: none"> ✔ to update the benefit-risk determination and to improve the risk management; ✔ to update the design and manufacturing information, the instructions for use and the labelling; ✔ to update the clinical evaluation; ✔ to update the summary of safety and clinical performance; ✔ to identify the need for preventive, corrective or field safety corrective action; ✔ to identify options to improve the usability, performance and safety of the device; ✔ to contribute to the post-market surveillance of other devices; and, ✔ to detect and report trends. <p>A PMS plan is required and details of the PMS plan are provided in Annex III.</p>	<p>The MDD mentions the conduct of PMS and PMCF but provides no detailed requirements. The MDR provides requirements for a PMS system within the manufacturer's QMS and the uses for the data gathered. Detailed requirements for a PMS plan, incorporating a PMCF plan, are provided. Specific reports of PMS are required to be prepared and updated periodically at a frequency dependent on the device classification. For class III and implantable devices, this report is subject to review by the notified body.</p> <p>For further information on PMS, see BSI White Papers 'The European Medical Devices Regulations – what are the requirements for vigilance reporting and post-market surveillance?' and 'Effective Post-market Surveillance – Understanding and Conducting Vigilance and Post-market Clinical Follow-up'.</p> <p>For further information on post-market clinical follow-up, see BSI White paper 'The post-market priority'.</p>

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		<p>Post-market clinical follow-up (PMCF) is a continuous process that updates the clinical evaluation. It is conducted in accordance with a PMCF plan that is an element of the overall PMS plan. PMCF can include:</p> <ul style="list-style-type: none"> ✓ gathering of clinical experience; ✓ collecting feedback from users; ✓ screening of scientific literature and of other sources of clinical data; ✓ evaluation of suitable registers; ✓ conducting PMCF studies. <p>Manufacturers of class I devices have to prepare a PMS report which is updated when necessary and made available to the competent authority upon request. Manufacturers of class IIa, class IIb and class III devices have to prepare a periodic safety update report (PSUR) for each device or each category or group of devices. The PSUR for class IIb and class III devices is updated at least annually and for class IIa devices when necessary and at least every two years.</p> <p>For class III devices or implantable devices, the PSURs is submitted to the notified body, who reviews the report and prepares an evaluation. The PSUR and notified body evaluation is made available to the competent authority.</p>	
Vigilance	<p>Article 10</p> <p>Competent authorities have to record and evaluate centrally device recalls or reports of events which might lead to or might have led to the death of a patient or user or to a serious deterioration</p>	<p>Articles 87 – 92</p> <p>Manufacturers have to report:</p> <ul style="list-style-type: none"> ✓ serious incidents, and ✓ field safety corrective actions. 	<p>The MDD outlined the responsibilities of competent authorities and the conformity assessment annexes incorporate requirements for manufacturers to report events. In the MDR, most of the information previously contained</p>

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	<p>in their state of health due to:</p> <ul style="list-style-type: none"> ✔ malfunction or deterioration in the characteristics and/or performance of a device, ✔ inadequacy in the labelling or the instructions for use. <p>The requirements for manufacturers to report are included in the conformity assessment procedures in the Annexes to the MDD. A significant amount of guidance on responsibilities of manufacturers and competent authorities is included in MEDDEV 2.12-1 revision 8 'Guideline on a medical devices vigilance system'.</p>	<p>A serious incident is associated with:</p> <ul style="list-style-type: none"> ✔ the death of a patient, user or other person, ✔ the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, or, ✔ a serious public health threat; <p>Additionally, there is a requirement for trend reporting of incidents that are exempt from reporting; that is to report any statistically significant increase in the frequency or severity of incidents that do not meet the reporting criteria but could have a significant impact on the risk-benefit analysis and present unacceptable risks to the health or safety of patients, users or others.</p> <p>The timelines for reporting events that are:</p> <ul style="list-style-type: none"> ✔ considered serious public health threats is two days; ✔ death or unanticipated serious deterioration in is ten days; and, ✔ all other events is 15 days. 	<p>in guidance has clearly been incorporated into the legal text. There is a change in terminology found in the MDR: what were previously called reportable events are now called serious incidents, whereas incidents or non-serious incidents refer to what were previously called non-reportable events. The terms adverse events and serious adverse events are used in the EU MDR only in the context of premarket clinical investigations. The exemption rules that obviated the need to report events have been reduced in number significantly; the only exclusion remaining is for expected side-effects that are clearly detailed in the product information and contained in the technical documentation. Additionally, the scope of reporting has been increased as temporary serious deterioration in health is explicitly reportable. The timelines for reporting events that are considered serious public health threats or death or unanticipated serious deterioration in health have remained unchanged at two and ten days respectively, but the timeline for reporting all other events has been decreased from 30 days to 15 days.</p> <p>For further information, see BSI White papers 'The European Medical Devices Regulations – what are the requirements for vigilance reporting and post-market surveillance?' and 'Do you know the requirements and your responsibilities for medical device vigilance reporting? A detailed review on the requirements of MDSAP participating countries in comparison with the European Medical Device Regulation 2017/745'.</p>

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Get in Touch

Smart Support is designed to outline the impact of the new regulatory changes, in order for your business to prepare to navigate the transition and implement the new requirements.

To access the full comparison table of the MDD and MDR as part of the MDR/IVDR Smart Support series and find out more about Compliance Navigator, contact us today.

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