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

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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 provides a comparison of some of the annexes of the MDD and MDR.

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
Product requirements	Annex I The MDD sets out 13 essential requirements (ERs) covering: ✓ General requirements, principally regarding risk; ✓ Chemical, physical and biological properties; ✓ Infection and microbial contamination; ✓ Construction and environmental properties; ✓ Devices with a measuring function;	Annex I The MDR sets out 23 GSPRs covering: ✓ General requirements, principally regarding risk; ✓ Products without a medical purpose; ✓ Chemical, physical and biological properties; ✓ Infection and microbial contamination; ✓ Devices incorporating a medicinal product;	Where there are 13 ERs in the MDD (and 16 in the AIMDD), there are 23 GSPRs in the MDR. The overall text and requirements are expanded, but the scope and topics are consistent overall with the MDD. Some topics such as clinical evaluation and medicinal consultation have moved from the requirements list into the articles, while other topics are new to the requirements list, including devices without a medical purpose and devices used by lay persons. A number of areas now have increased emphasis and more

Topic	Medical Devices Directive (93/42/EEC), as amended	Medical Devices Regulation ((EU) 2017/745)	Comments
	✓ Protection against radiation; ✓ Active devices; and ✓ Information supplied by the manufacturer.	✓ Devices with substances that are absorbed or locally dispersed, ✓ Devices incorporating materials of biological origin; ✓ Construction of devices; ✓ Interaction with the environment; ✓ Devices with a diagnostic or measuring function; ✓ Protection against radiation; ✓ Electronic programmable systems; ✓ Active devices and devices connected to them; ✓ AIMDs; ✓ Mechanical and thermal risks; ✓ Devices supplying energy or substances; ✓ Devices for use by lay persons; and, ✓ Information supplied with the device.	explicit requirements, such as electronic programmable systems, nanomaterials, devices with substances that are absorbed or locally dispersed, and substances that are carcinogenic, mutagenic or endocrine-disrupting. The format of several of the GSPRSs highlights aspects to be addressed in the manufacturer's risk management processes. The section on information to be provided with the device has increased detail. For further information, see BSI White paper 'General Safety and Performance Requirements (Annex 1) in the New Medical Device Regulation – Comparison with the Essential Requirements of the Medical Device Directive and Active Implantable Device Directive' and BSI Compliance Navigator Blog 'Will you need more space on your labels?'.
Declaration of conformity	The conformity assessment annexes of the MDD indicate that the manufacturer has to draw up a written declaration of conformity. This declaration has to cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference. The declaration of conformity has to be kept by the manufacturer for the same period as the technical documentation.	Annex IV The content of the EU declaration of conformity are specified as: ✓ Details of the manufacturer, and, if applicable, its authorised representative; ✓ Statement that the EU declaration of conformity is responsibility of the manufacturer; ✓ Product description and intended purpose; ✓ Device identifiers of the UDI; ✓ Risk class of the device;	The declaration of conformity is the legal document in which the manufacturer declares that the product is in conformance to the requirements of the legislation. It is referred to in all the conformity assessment routes in the MDD but the content is not specified in detail. In the MDR, the content of the declaration of conformity is set out.

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		✓ A statement that the device covered by the declaration is in conformity; ✓ References to any CS used; ✓ Where applicable, the notified body, and conformity assessment procedure performed; ✓ Identification of any applicable certificate(s); ✓ Signature, place and date of issue of the declaration with name and function of the signatory and for whom it was signed.	

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 annexes 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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