Patient Guard
Medical Device Quality & Regulatory Assurance

Medical Device Technical File - Checklist

Regulation: Medical Device Regulations EU 2017/745

This EU Medical Device Regulation (MDR) 2017/745 checklist is a great tool to enable you to ensure you meet all the document compliance requirements of Annex II and Annex III for your medical device.

It includes helpful instructions and signposting as to what information should go where within your technical file. The checklist covers all types of medical devices so its important to identify what sections will be applicable to your medical device.

For help and assistance, please reach out to us at Patient Guard and we can provide regulatory assistance in ensuring your compliance journey.

Technical File Sections	Information/Document Needed	Applicable (Y/N) (If No please explain why)	Complete
Device Description			
Device Name(s)	The trade name of the medical device(s) which will be placed onto the market		◯
General Description	A General Description and overview of the medical device and inclusion of any photographs or drawings which help to identify any important parts of the of the medical device		◯
UDI-DI	Provide the first section of the UDI number that identifies who the manufacturer is and the product. The UDI must be purchased from one of the EU authorised organisations that issue UDI numbers (e.g. GTIN barcodes) such as GS1		◯
Product Codes/ Catalog Numbers	Provide any device identifying codes, such as product codes or catalog numbers		◯
Intended Use, Intended User, Intended Environment of Use	What the intended purpose and use of the device will be along with who the intended users are, where the device will be used, and in the environment the devices will be used.		◯
Contraindications	Detail any contraindications associated with the use of the medical device. For example; not to be used on individuals under the age of 18 years old etc.		◯
Principles of Operation	Provide Information to help the reader of the technical file to understand how the medical device operates		◯
Rationale for Product as a Medical Device	Provide a statement detailing why the product is considered to be a medical device from the definition of a medical device according to Article 2 of MDR 2017/745		◯
Risk Classification of Device(s)	A statement detailing the risk classification rule chosen from Annex XIII MDR 2017/745 and why this rule has been chosen		◯

Technical File Sections	Information/Document Needed	Applicable (Y/N) (If No please explain why)	Complete
Novel Features	Details of what are the novel features of the medical device? Such as new features or designs that have not previously been used on the market in any other medical devices (If applicable)		◯
Accessories	Detail any accessories applicable to the medical device. Accessories are items that can be used along with the medical device to help it achieve its purpose, but are not medical devices in their own right. For Example, a watch would be an accessory to a software app.		◯
Configuration for variants	Detail the configuration for any variants of the medical device. For example there maybe a range of products that are the same type of medical device, and these may have slightly different functions across the range (if applicable)		◯
Functional Elements	Detail the functional elements of the medical device. What are the main parts that perform the intended use of the device		◯
Raw Materials	Provide a list of the raw materials that are used to manufacture the medical device. (Only applicable to physical devices. A software app for example would not need this)		◯
Technical Specifications	Provide any technical specifications for the medical device, this might include specifications from a technical manual for example, such as IP ratings, Electrical Voltage etc.		◯
Previous or similar generations of Device(s)	Provide details of any previous generations of medical device and/or any similar medical devices that are on the market (this can include competitor devices)		◯
Information Supplied by the Manufacturer			
Labelling	Include the labelling of the medical device, ensure that the labelling contains necessary symbols required for Medical Devices according to ISO 15223-1 and Annex I and Annex V of MDR 2017/745		◯
Instructions for Use	Include the instructions for use, ensure that instructions for use are inline with the requirements of Annex I of MDR 2017/745		◯
Marketing Brochures	Provide any marketing information such as brochures that include medical device claims etc.		◯

Technical File Sections	Information/Document Needed	Applicable (Y/N) (If No please explain why)	Complete
DESIGN AND MANUFACTURING INFORMATION			
Software Devices or Devices that incorporate Software			
Software Risk Classification	A document detailing the software risk classification according to IEC 62304 based on your assessment of the classification criteria		◯
Software development plan	A software development plan document inline with the requirements of IEC 62304		◯
Software Requirements Analysis	A software development requirements analysis document with the requirements of IEC 62304		◯
Software Architectural Design	Only if software is B or C Risk Class See IEC 62304		◯
Software Detailed Design	Only if software is B or C Risk Class See IEC 62304		◯
Devices that are not stand alone software			
Design Specifications	Provide information relating to the design of the medical device including any design plans and design specifications. Design and Development should follow the requirements set out in the medical device quality management system standard ISO 13485 and any associated documentation provided within the technical file. For any medical devices that need to follow specific design requirements from a specific medical device standard, this information should be included.		◯
Device Drawings	If applicable include any device drawings, such as CADD files etc.		◯
Bill of Materials	Provide a full list of each material and component that the medical device is constructed from.		◯
Material Safety Data Sheets	Provide Material Safety Data Sheets for all materials that the medical device is constructed from		◯

Technical File Sections	Information/Document Needed	Applicable (Y/N) (If No please explain why)	Complete
Manufacturing Processes	Provide all manufacturing process documentation, ensure that any addatives used in the manufacturing process are also included.		◯
Design and Manufacturing Sites	Provide the company names and addresses of any 3rd party suppliers who have performed any design or manufacturing processes (if applicable)		◯
General Safety & Performance Requirements (GSPR)			
GSPR Checklist	Provide a checklist of all the applicable GSPR requirements for your medical device of Annex I of MDR 2017/745. The checklist should include any applicable standards used to demonstrate how you will meet compliance for each applicable clause		◯
Risk Management			
Risk Management Plan	A Risk Management Plan for the device inline with the requirements of ISO 14971 (medical device risk management standard)		◯
Risk identification/analysis/ evaluation	Risk Management documentation covering the requirements set out in ISO 14971		◯
Management Review Statement	A statement from the risk management review meeting in line with the requirements set out in ISO 14971 that explains all the risks have been reviewed and the outcomes etc.		◯
VERIFICATION & VALIDATION			
Product Validation			
Product Testing Reports	Information should be provided in the form of testing reports showing what tests have been carried out on the device to demonstrate that it performs safely and as intended within its normal intended use conditions. If there are standards specific to how this is completed for your type of medical device then this information should be included here.		◯
Packaging Validation			
Packaging Testing Reports	Packaging testing should be conducted on the medical device to ensure that it still operates as intended, and that the packaging is robust and protects the device during; storage, handling, transportation and cleaning in the environmental conditions you have specified on the labelling/IFU.		◯

Technical File Sections	Information/Document Needed	Applicable (Y/N) (If No please explain why)	Complete
Software Verification & Validation			
Software Unit Implementation	A document detailing how the software has been implemented. Level of detail needed is dependent on if the software safety class is A, B or C IEC 62304		◯
Software integration and integration testing	Only if software is B or C Risk Class See IEC 62304		◯
Software System testing	A document detailing software system testing. Level of detail needed is dependent on if the software safety class is A, B or C, IEC 62304		◯
Software Release	A document detailing how software will be released. Level of detail needed is dependent on if the software safety class is A, B or C, IEC 62304		◯
Electrical Safety			
Basic Electrical Safety Reports	Provide a report that details that the provisions within IEC 60601-1 and other applicable electrical safety standards have been addressed		◯
EMC Testing Reports	Provide testing reports relating to Electromagnetic Compatability (EMC) inline with the requirements of IEC 60601-1-2		◯
Sterilisation			
Ethylene Oxide Sterilisation	If the product is sterilised using ethylene oxide then documentation should be provided that sterilisation process has been carried out inline with the requirements of standard ISO 11135 and that residuals testing has been carried out as required by ISO 10993-7.		◯
Gamma Radiation Sterilisation	If the product is sterilised using gamma radiation then documentation should be provided that sterilisation process has been carried out inline with the requirements of standard ISO 11137		◯
Steam Sterilisation	If the product is sterilised using steam then documentation should be provided that sterilisation process has been carried out inline with the requirements of standard ISO 17665		◯
Packaging for terminally sterilisaed medical devices	Documentation should be provided for medical device packaging validation when terminally sterilisaed inline with the requirements of ISO 11607		◯

Technical File Sections	Information/Document Needed	Applicable (Y/N) (If No please explain why)	Complete
Biological Evaluation			
Biological Evaluation Plan	Provide a Biological Evlauation Plan writen by a qualifed toxicologist in line with the requirements of ISO 10993 biological safety standard for medical devices that have direct or indirect contact with patients		◯
Biological Evaluation Report	Provide a Biological Evlauation Report writen by a qualifed toxicologist in line with the requirements of ISO 10993 biological safety standard for medical devices that have direct or indirect contact with patients		◯
Biological Evaluation Test Reports	Provide testing reports for any biological endpoint testing that has been completed on the medical device, detailed within the Biological Evlauation Plan. For example, cytotoxicity, extractables and leachables, sensitization, implantation, haemocompatability, genotoxicity etc. Ensure testing laboratories are accredited and GLP compliant, reports should be written by qualifed professionals.		◯
Usability Engineering			
Usability Engineering Report	Provide evidence that usability has been taken into account for when the device is used. This should follow the principles provided in ISO 62366 usability engineering standard.		◯
Clinical Evaluation			
Clinical Evaluation Plan	A Clinical Evaluation Plan inline with the requirements of MEDDEV 2.7/1 rev 4, annex XIV part A and article 61 of MDR 2017/745, as well as any applicable MDCG guidance documents.		◯
Declaration of Intent	A Declaration of Intent inline with the requirements of MEDDEV 2.7/1 rev 4		◯
Clinical Evaluation Report	A Clinical Evaluation Report inline with the requirements of MEDDEV 2.7/1 rev 4, annex XIV part A and article 61 of MDR 2017/745, as well as any applicable MDCG guidance documents.		◯
Clinical Literature Search results	downloaded lists from live searches on clinical journal search engines		◯

Technical File Sections	Information/Document Needed	Applicable (Y/N) (If No please explain why)	Complete
Clinical Literature Papers	PDF's of Clinical Papers used or referenced		◯
Manufacturer Unpublished Data	Include any unpublished data that has been used as clinical evidence. This may include the results from clinical trials.		◯
Post Market Surveillance			
Post Market Surveillance Plan	A plan on how Post Market Surveillance will be carried out inline with any applicable MDCG guidence documents and Articles 83, 84, and 87 of MDR 2017/745		◯
Post Market Clinical Follow-up Plan	A plan on how PMCF will be carried this should be inline with the requirements of Annex XIV part B of MDR 2017/745		◯
Software Specific PMS			
Software Maintenance Process	A software maintenance process document inline with the requirements of IEC 62304		◯
Software Configuration Management Process	A software configuration management process document inline with the requirements of IEC 62304		◯
Software Resolution Process	A software resolution process document inline with the requirements of IEC 62304		◯
Declaration of Conformity			
Declaration of Conformity	Signed Document inline with the requirements of Annex VI of EU MDR 2017/745		◯

Patient Guard
Medical Device Quality & Regulatory Assurance

About Patient Guard

Established in 2017, **Patient Guard** is a leading consultancy firm specializing in EU, UK, and FDA regulatory affairs and quality assurance services within the Medical Device and In Vitro Diagnostics (IVD) industry. We are a trusted partner for global organisations across the UK, US and Europe, and we have offices located in the UK and Germany.

With a commitment to driving innovation and excellent customer service, we offer a full range of comprehensive solutions tailored to help our clients navigate regulatory compliance and optimize their quality management protocols. Our team of specialists utilise their extensive expertise and technical knowledge to achieve the safety, efficacy, and industry standards of medical devices and IVDs.

At Patient Guard, we support clients through the dynamic and evolving landscape of medical device regulation by bringing clarity to complexity and ensuring client satisfaction at every step of the way.

About David Small *Founder/CEO*

With over two decades of experience in the medical device industry, **David Small** harnesses a combination of regulatory expertise and technical insight to his role as the founder of Patient Guard.

Initially a biomedical scientist in the NHS, David's qualifications include an MSc and PhD in Analytical Bioscience, Drug Design and Chemistry. He then served as a higher medical device specialist across a variety of biomedical sectors before founding Patient Guard Limited.

David's extensive background in regulatory affairs and quality assurance has cultivated a reputation for adeptly navigating the complex regulatory environment with precision and consideration. His dedication to making compliance accessible has enabled Patient Guard to continue driving success for its global clientele, ensuring that they remain at the forefront of medical device compliance.

Contact us today for more information:

UK Office:
Patient Guard Ltd
Lancaster House,
Amy Johnson Way,
Blackpool,
Lancashire, FY4 2RP

EU Office:
Patient Guard Europe UG
(haftungsbeschrankt)
Hauffstraße 41
73765 Neuhausen
Deutschland / Germany

info@patientguard.com
+44 (0) 1253 522 375
www.patientguard.com