

Product List and Application MDR
QMS part



Name of Legal Manufacturer

Address Legal Manufacturer

EUDAMED Single Registration No.
MDR (EU) 2017/745

MDR (EU) 2017/745

[Annex IX Chapter I, Section 2 and 3](#)

Reason for submission of product list

[Select an item](#)

Product List and Application MDR QMS part



Declaration of the applicant

I hereby apply for the assessment of my quality management/assurance system with respect to the product(s) listed hereafter.

I hereby declare

- that no application has been lodged with any other notified body for the same device-related quality system.

In relation to the quality assurance system I assure

- to fulfil the obligations imposed by the medical device regulation 2017/745 on establishing, documenting, implementing and maintaining a quality management system;
- to keep the approved quality system adequate and efficacious;
- to institute and keep up to date a system to review experience gained from post-market surveillance, including the provisions referred to in Annex III, and to inform the notified body about initiated corrective and / or preventive actions;
- to notify the competent authorities and TÜV Rheinland LGA Products GmbH of the following as described in accordance with Article 87:
 - a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;
 - b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country. The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 92.
- to notify the competent authorities and TÜV Rheinland LGA Products GmbH of the following as described in accordance with Article 88:

Any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

 - for applications according to Annex XI Part A:
 - I ensure and declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III and meet the requirements of this Regulation which apply to them.

Product List and Application MDR QMS part



Additionally I declare

- that I have not withdrawn an application with another notified body prior to the decision of that notified body
 - that I provide all information about any previous application with another notified body prior to the decision of that notified body for the same conformity assessment that has been withdrawn, including information about the refusal by that other notified body, as applicable
 - to submit to the notified body the relevant documentation as defined in Annex IX, Chapter, I Section 2.1;
 - to keep the relevant documentation including documents provided by TÜV Rheinland LGA Products GmbH for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market in order to fulfil Chapter II Article 10 Par. 8
 - that all listed devices meet the general safety and performance set out in Annex I;
 - to inform TÜV Rheinland LGA Products GmbH without delay in case of inquiries by any competent authority regarding the products covered by this application;
 - to inform TÜV Rheinland LGA Products GmbH about any planned substantial changes to the approved quality management system (e. g. procedural changes regarding design and development, production, or end control), or the products/product range covered by it
 - and not to implement such substantial changes prior to a notification from TÜV Rheinland LGA Products GmbH to do so.
- Note: For guidance on significant change notification refer to NBOG best practice guide 2014-3;
- to submit an informal application for certificate re-assessment to the notified body, at least 6 months before expiry of the certificate. A different date may be agreed by means of a contract:

TÜV Rheinland LGA Products GmbH
Certification Office Medical
Am Grauen Stein 29
51105 Cologne
Germany
E-Mail: medical-products@de.tuv.com

In case of an application for a conformity assessment procedure according to Annex XI Part A (Production quality assurance) the manufacturer shall attach a copy of the EU type-examination certificate referred to in Section 4 of Annex X and relevant notified body examination reports, as applicable.

As a manufacturer who does not have a registered place of business in an EU member state, (including states holding an appropriate agreement with the EC), I additionally declare

- to designate per generic device group one authorized representative established in the Community;
- that the designation is accepted in writing by the authorised representative

Product List and Application MDR
QMS part



- to inform TÜV Rheinland LGA Products GmbH in case the authorized representative has changed;
- that the authorized representative has permanently available and keeps the relevant documentation including documents provided by TÜV Rheinland LGA Products GmbH to allow the authorised representative to fulfil the tasks mentioned in Article 11(3) for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.
- to sign an agreement with the authorized representative which enables the authorised representative to fulfil the delegated tasks as defined in Article 11(3).

Product List and Application MDR
QMS part



+	Code of facilities	Scope of facilities	Name of facility	Address of facility
	EAR (1)	European Authorized Representative	<input type="text"/>	<input type="text"/>
	IMF (1)	Internal Manufacturing Facility	<input type="text"/>	<input type="text"/>
	EMF (1)	External Manufacturing Facility	<input type="text"/>	<input type="text"/>
	R&D(1)	Research & Development	<input type="text"/>	<input type="text"/>
	OEM(1)	Original Equipment Manufacturer	<input type="text"/>	<input type="text"/>
	Sterilization facility Radiation (1)	Select an item	<input type="text"/>	<input type="text"/>
	Sterilization facility Gas (1)	Select an item.	<input type="text"/>	<input type="text"/>
	Sterilization facility Heat	Select an item	<input type="text"/>	<input type="text"/>

Product List and Application MDR
QMS part



	(1)			
	Sterilization facility: Other sterilization methods (1)	Select an item	<input type="text"/>	<input type="text"/>

Please add lines as required!

Product List and Application MDR
QMS part



No.	Product name [as listed on label]	General product group name	Classification Rule including subclause according to Annex VIII	Device Class	Device codes [Commission implementing regulation (EU) 2017/2185]	Allocation of class IIb products into Generic Device Groups	GMDN number for class IIb products only	Basic UDI-DI for class III products and IIb implantable products	TD/DD identifier	Summary list of related facilities [choose codes from above]	Code of EU-REP [choose from above]
1	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an item	Select an item	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
2	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an item	Select an item	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
3	<input type="text"/>	<input type="text"/>	<input type="text"/>	Select an item	Select an item	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Devices included manufactured utilising animal tissue which is rendered non-viable or utilising non-viable products derived from animal tissue, as referred to in Regulation (EU) No 722/2012? no yes, line no

Date

Location

Legally binding signature