Product List and Application MDR Technical documentation assessment, Annex IX, chapter II

TÜVRheinland®

Name of Legal Manufacturer	
Address Legal Manufacturer	
EUDAMED Single Registration No. MDR (EU) 2017/745	
MDR (EU) 2017/745	Annex IX, Chapter II, Section 4
Reason for submission of product list	Select an item

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Declaration of the applicant
I hereby apply for the assessment of the technical documentation with respect to the product(s) listed hereafter.

I hereby declare that in addition to the declarations provided with the application on the assessment of the quality management system according to MDR 2017/745 Annex IX, Chapter I, Section 2 and 3, I hereby declare that no application has been lodged with any other notified body for the same device-related technical documentation assessment.

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☐ that I have not withdrawn an application with another notified body prior to the decision of that notified body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with another notified body prior to the decision of that notified body for the same conformity assessment that has been withdrawn, including information about the refusal by that other notified body, as applicable.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 II and III;
- 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 change to the approved devices (i.e. those which may affect conformity with the general safety and performance requirements), to the approved design of the device, to the intended use of or claims made for the device, with the conditions prescribed for use of the product or to any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with referred to in Sections 5 and 6 of Annex IX.
- 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

Note: Additional documents being part of this application will be requested at different stages throughout the initial certification process.
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 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
- 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).

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

	Sterilization facility: Other sterilization methods (1)	Select an item		

Please add lines as required!

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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				Select an item	Select an item						
2				Select an item	Select an item						
3				Select an item	Select an item						

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