Product List und Application MDR
Product Verification

TÜVRheinland®

Name of Legal Manufacturer	
Address Legal Manufacturer	
EUDAMED Single Registration No. MDR (EU) 2017/745	
MDR (EU) 2017/745	Annex XI, Part B
Reason for submission of product list	Select an item

Product List und Application MDR Product Verification	TÜVRheinland®

Declaration of the applicant
I hereby apply for the assessment of product verification 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 product verification.
- that the below listed products of Class IIb or Class III conform to the type described in the MDR type-examination certificate and meet the requirements of this Regulation which apply to them. (Please attach copy of the MDR type examination certificate);
- that the below listed products of Class IIa are manufactured in conformity with the technical documentation referred to in Annex II and III and meet the requirements of this Regulation which apply to them;
- that all the measures necessary to ensure that the manufacturing process produces devices which conform to the type described in the MDR type-examination certificate (class IIb and III devices) / to the devices described in the technical documentation referred to in Annex II and III (class IIa devices) and to the requirements of the Regulation which apply to them;
- to maintain and apply documents to ensure homogeneous production;
- 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, the procedures ensuring compliance with the obligations of the manufacturer resulting from the provisions on vigilance and post-market surveillance system set out in Chapter VII and to inform the notified body about initiated corrective and / or preventive actions; specifically
- 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.

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 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), or the intended use of or claims made for the device or with the conditions prescribed for use of the product, or to substances 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.

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	Select an item		

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

Please add lines as required!

Product List und Application MDR
Product Verification

TÜVRheinland®

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