Product List and Application MDR
QM part

TÜVRheinland®

Name of Legal Manufacturer:	Softneta UAB
Address of Legal Manufacturer:	Baršausko str. 59B LT-51423 Kaunas Lithuania
EUDAMED Single Registration No:	
MDR (EU) 2017/745:	Annex IX Chapter I, Section 2 and 3
Reason for submission:	New product list

This Product List and Application replaces all previous applications.
Please provide the signed version of this document (note: not all data will be printed) and the Excel file with all data to your TÜV Rheinland contact.

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.

Additionally I declare ***(Please mark check box accordingly!)***

☐ **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 requirements 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 substantial 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
E-mail for vigilance cases: medical-vigilance@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 authorised 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 authorised representative has changed;
- that the authorised 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 authorised representative which enables the authorised representative to fulfil the delegated tasks as defined in Article 11(3).

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FACILITIES:

Code of facility	Scope of facility	Legal entity name of facility	Address of facility
EAR(1)	European authorised Representative	Softneta UAB	Baršausko str. 59B, Kaunas LT-51423, Lithuania
IMF(1)	Internal Manufacturing Facility	Softneta UAB	Baršausko str. 59B, Kaunas LT-51423, Lithuania
EMF(1)	External Manufacturing Facility	not applicable	
IR&D(1)	Internal Research & Development	Softneta UAB	Baršausko str. 59B, Kaunas LT-51423, Lithuania
ER&D(1)	External Research & Development	not applicable	
S_RAD(1)	Sterilization facility Radiation - Please select method	not applicable	
S_GAS(1)	Sterilization facility Gas - Please select method	not applicable	
S_HEAT(1)	Sterilization facility Heat - Please select method	not applicable	
S_OTH(1)	Sterilization facility Other : Please specify	not applicable	

Please add lines as required!

Note: To add line, please select and copy entire corresponding row, and insert copied row.

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PRODUCTS:

Note: Please provide an information for all columns (also the blue columns which will not be printed).

No.	Product name (as listed on label)	Product name (using nomenclature of basic UDI-DI)	basic UDI-DI code	Medical Device Code (for all medical devices)	Generic Device Group (ENMD code on level 4; Letter + 6-digits; if no level 4 level exists use next upper level)	Classification of product and classification rule resulting in highest risk class		Summary list of related facilities (use facility codes from Facilities table, i.e IMF(1), IR&D(1))	Code of EU-REP (use facility No from Facilities table)
						Device Class	Classification Rule including subclause according to Annex VIII		

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1	MedDream	Software	(01)04779049590105(10)MDSY7510	MDA 0315 Standalone software	Z119082	IIb	Rule 11. Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes, if such decisions have an impact that may cause a serious deterioriation of a person's state of health or a surgical intervention.	EAR(1) IMF(1) IR&D(1)	EAR(1)

Please add or delete lines as required!

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	2020-07-23	
Location	Date	Legally binding signature

The Notified Body TÜV Rheinland LGA Products GmbH confirms that the infomation provided on the Product List and Application is covered by the EU conformity assessment procedure as certified by MDR (EU) certificate No: HZ 1992126-1

2021-06-02	
Date	Certifier of the Notified Body signature