

Applicant:	Name of organisation
Order number:	Order number
Regulation and Annex:	Regulation (EU) 2017/745 on medical devices (MDR), Annex IX, Chapter I and III

TÜV Rheinland LGA Products GmbH was commissioned by your organization to perform a conformity assessment procedure according to Regulation (EU) 2017/745 (MDR).

The requirement for performing the conformity assessment procedure is to lodge a complete application according to Annex IX, chapter 1, 2.1.

In the initial phase, the completeness of your application for MDR is reviewed.

Please fill in each line of the following table with references to product and quality management documents, which cover the requirements of this checklist.

Afterwards, please send the completed list to TÜV Rheinland LGA Products GmbH.

	Requirement (see MDR Annex IX and Annex XI part A)	Reference to documents and/or comment of the organization	Review remarks (to be filled out only by TRLP)
1. General			
1	Signed „Product List and Application MDR Annex IX (QMS part) and MDR Annex XI part A“ (MS-0030360)	Signed hand-written: To be provided electronically (as Excel file) and in original hardcopy or fax OR Electronically signed: Electronic signatures must comply with advanced or qualified signatures according to Regulation (EU) 910/2014 (eIDAS). TÜV Rheinland must be either able to verify that these criteria are fulfilled, or the applicant has to declare <u>once</u> that the above-mentioned criteria are fulfilled (by a hand-written signed declaration) Product List and Application MDR (QM part) YYYY-MM-DD	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
2	Evidence of the registration for the additional trade name or trade mark (used on the label; MDR Annex I clause 23.2.(c))	Please provide relevant registration records	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
2. Information on the product			
3	A draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
4	A summarizing description of each device and the intended use of the device/device groups including a description of the specific medical purpose	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable

	Requirement (see MDR Annex IX and Annex XI part A)	Reference to documents and/or comment of the organization	Review remarks (to be filled out only by TRLP)
	Note: Might be covered by the EU Declaration of conformity		
5	Product brochure or product catalogue covering the products in scope (optional)	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
3. Information on the QM system			
6	Top-level QM system document (e.g. quality manual)	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
7	A list of all valid QM procedures/work instructions with release date for every location of the QM system	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
8	A documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under this Regulation and the undertaking by the manufacturer in question to apply those procedures	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
9	A description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable

Review Checklist for Application Package according to MDR



	Requirement (see MDR Annex IX and Annex XI part A)	Reference to documents and/or comment of the organization	Review remarks (to be filled out only by TRLP)
10	Procedures for the clinical evaluation, pursuant to Article 61 and Annex XIV	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
11	Documentation on the manufacturer's post-market surveillance system according to MDR	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
12	Documentation on the manufacturer's post market clinical follow-up (PMCF) plan.	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
13	The procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92.	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
14	A description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures.	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
15	Documentation on the clinical evaluation plan.	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable

Review Checklist for Application Package according to MDR



	Requirement (see MDR Annex IX and Annex XI part A)	Reference to documents and/or comment of the organization	Review remarks (to be filled out only by TRLP)
16	A description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
17	Documentation about methods to communicate effectively with competent authorities, notified bodies, economic operators, clients and/or other stakeholders.	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
18	Procedures for verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable

The following section shall only be filled by customers without a valid MDD/AIMDD or EN ISO 13485 certificate issued by TÜV Rheinland LGA Products GmbH:

	Requirement (see MDR Annex IX and Annex XI part A)	Reference to documents and/or comment of the organization	Review remarks (to be filled out only by TRLP)
19	General Agreement with TRLP (provided with Quotation package)	To be provided in original hardcopy or fax	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
20	Procedures for management of modifications to the devices covered by the system	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
21	Responsibility of the management	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
22	Resource management, including selection and control of suppliers and sub-contractors	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
23	Procedures of risk management as set out in in Section 3 of Annex I	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable

Review Checklist for Application Package according to MDR



24	Identification of applicable general safety and performance requirements and exploration of options to address those requirements	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
25	Product realisation, including planning, design, development, production and service provision	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
26	Procedures for reporting serious incidents and field safety corrective actions in accordance with Article 87 and 88	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
27	Management of corrective and preventive actions and verification of their effectiveness	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable
28	Processes for monitoring and measurement of output, data analysis and product improvement	Please indicate the document name and revision number and/or additional information	<input type="checkbox"/> available <input type="checkbox"/> missing <input type="checkbox"/> not applicable

Responsible contact for questions: 	Name of representative: Phone number:
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