Product List and Application MDR

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR

TÜVRheinland®

Name of Legal Manufacturer (shall be identical as given in General Agreement with TRLP):	ChangZhou BoMedent Medical Technology Co., Ltd.
Additional registered trade name or registered trade mark of the manufacturer (used on the label; MDR Annex I clause 23.2.c):	BOMEDENT
Address of Legal Manufacturer:	No.9 Changyang Road, West Taihu Science and Techology Industrial Park, Changzhou, 213000 Jiangsu, P.R. China
EUDAMED Single Registration No:	CN-MF-000010413
MDR (EU) 2017/745:	Annex IX Chapter I
Reason for submission:	Application according to (EU) 2023/607 (may also be an Initial application MDR)

Changzhou BomeDent Medical Technology Co., Ltd. 常州博美医疗科技有限公司 320412605307

☐ **This Product List and Application replaces all previous applications.** In case of changes to a previous version of the Product List and Application, please mark all changes in red font color and in **bold.** In case of deleting products from the portfolio, please cross out the relevant products.

☑ **This Product List and Application is an addendum to the initial application** dated 2022-06-29.
(Please list only devices for which EU 2023/607 Confirmation Letter is requested)

Please provide a legally binding signed version of this document by fax, 2-fold by post (note: not all data will be printed) or electronically signed (advanced or qualified signature according to eIDAS Regulation (EU) No 910/2014). In addition please provide this Product List and Application as as Excel file.

Product List and Application MDR

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR

TÜVRheinland®

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:

- **that I have not withdrawn an application with another notified body prior to the decision of that notified body, OR**
- **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;
- that used registered trade name(s) and/or registered trade mark(s) of the manufacturer used in accordance with MDR 2017/745, Annex I, 23.2 (c) are not separate legal persons.
- 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

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).

Product List and Application MDR

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR

TÜVRheinland®

FACILITIES:

Code of facility	Scope of facility	Legal entity name of facility	Address of facility	EUDAMED Single Registration No.
EAR(1)	European authorised Representative	Caretechion GmbH	Niederrheinstr.71,40474 Duesseldorf, Germany	DE-AR-000005946
IMF(1)	Internal Manufacturing Facility	ChangZhou BoMedent Medical Technology Co., Ltd.	No.9 Changyang Road, West Taihu Science and Techology Industrial Park, Changzhou, 213000 Jiangsu, P.R. China	
EMF(1)	External Manufacturing Facility	N/A	N/A	
IR&D(1)	Internal Research & Development	ChangZhou BoMedent Medical Technology Co., Ltd.	No.9 Changyang Road, West Taihu Science and Techology Industrial Park, Changzhou, 213000 Jiangsu, P.R. China	
ER&D(1)	External Research & Development	N/A	N/A	
S_RAD(1)	Sterilization facility Radiation - Please select method	N/A	N/A	
S_GAS(1)	Sterilization facility Gas - Please select method	N/A	N/A	
S_HEAT(1)	Sterilization facility Heat - Please select method	N/A	N/A	
S_OTH(1)	Sterilization facility Other : Please specify	N/A	N/A	

Please add lines as required!

Note: To add line, please select and copy entire corresponding row, insert copied row and adapt the numbers in brackets (e.g. S_RAD (1), S_RAD (2)....

Product List and Application MDR

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR

TÜVRheinland®

PRODUCTS:

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

No.	Product name or Trade Name (as listed on label)	Type of device using terminology of Basic-UDI-DI, EMDN or GMDN	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN) *Please use EMDN code 4th level (EMDN code on level 4: Letter + 6 digits. If no level 4 exists, use next upper level)*	Classification of product and classification rule resulting in highest risk class: Device Class	Classification of product and classification rule resulting in highest risk class: Classification Rule including subclause according to Annex VIII	Summary list of related facilities *(use facility codes from Facilities table, i.e IMF(1), IR2D(1))*	Code of EU-REP *(use facility No from Facilities table)*	Technical Documentation identifier *(if the TD is ready for submission)* **or** declared date of submission of the technical documentation **[YYYY-MM]** *(if the TD is not ready yet for submission)*	Regulation (EU) 2023/607: If the MDR device is intended to substitute legacy device, identification of the corresponding MDD/AIMDD device *Please list the devices covered by the current MDD certificate which are intended to be discontinued but to be substituted by the device as specified in columns B*	Regulation (EU) 2023/607: MDD/AIMD Certificate(s) reference of the devices under MDR application and the notified body Identification *Please refer to the MDD/AIMD certificate(s) covering devices listed in columns B and/or E*
1	Dental Electrical Motors Model: Marc III	INSTRUMENTS FOR DENTAL TREATMENT UNITS	697107537MarcUL	MDA 0311 Active non-implantable dental devices	Z121101	IIa	Rule 9 Sun-clause 1	IMF(1), IR&D(1)	EAR(1)	BMD/CE-MEM	N/A	DD 60143320 0001 #0197
2	Dental Electrical Motors Model: Endo wise	INSTRUMENTS FOR DENTAL TREATMENT UNITS	697107537EndowiseWR	MDA 0311 Active non-implantable dental devices	Z121101	IIa	Rule 9 Sun-clause 1	IMF(1), IR&D(1)	EAR(1)	BMD/CE-MEM	N/A	DD 60143320 0001 #0197
3	Dental Electrical Motors Model: Marc Eco	INSTRUMENTS FOR DENTAL TREATMENT UNITS	697107537MarcEcoSR	MDA 0311 Active non-implantable dental devices	Z121101	IIa	Rule 9 Sun-clause 1	IMF(1), IR&D(1)	EAR(1)	BMD/CE-MEM	N/A	DD 60143320 0001 #0197
4	Dental Electrical Motors Model: iBon Mini	INSTRUMENTS FOR DENTAL TREATMENT UNITS	697107537iBonMiniQ9	MDA 0311 Active non-implantable dental devices	Z121101	IIa	Rule 9 Sun-clause 1	IMF(1), IR&D(1)	EAR(1)	BMD/CE-MEM	Dental Electrical Motors Model: iRoot Pro	DD 60143320 0001 #0197
5	Dental Electrical Motors Model: iBon Mini-SE	INSTRUMENTS FOR DENTAL TREATMENT UNITS	697107537iBonMiniSEY2	MDA 0311 Active non-implantable dental devices	Z121101	IIa	Rule 9 Sun-clause 1	IMF(1), IR&D(1)	EAR(1)	BMD/CE-MEM	Dental Electrical Motors Model: iRoot Pro	DD 60143320 0001 #0197
6	Apex Locators Model: iRoot apex	VARIOUS DENTAL STOMATOLOGY INSTRUMENTS	697107537iRootapexDV	MDA 0311 Active non-implantable dental devices	Z121190	IIa	Rule 10 Sub-clause 1 Indent 3	IMF(1), IR&D(1)	EAR(1)	BMD/CE-RCM	N/A	DD 60143320 0001 #0197

Please add or delete lines as required!

Product List and Application MDR

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR

TÜVRheinland®

Changzhou	2024-04-16	Bai Xue.
Location	Date	Legally binding signature

With signature of this application, the applicant confirms the validity and the accuracy of the data entered into the form sheet as basis for the extension of the MDD certification covering the listed articles within the requirements and the intent of regulation (EU) 2023/607.
The applicant also acknowledges that the general agreement executed between the manufacturer and TÜV Rheinland LGA Products GmbH (TRLP) on certification services including the signed PZO applies also to all activities undertaken in execution of regulation (EU) 2023/607 resulting from this application, thus confirming that this application also fulfills the requirement defined in (EU) 2023/607 that there be a written agreement in place between legal manufacturer and Notified Body latest by September 26, 2024.

The Notified Body TÜV Rheinland LGA Products GmbH confirms receipt of the application for conformity assessment procedure.

2024-04-30	Jason Pan
Date	Signature (certifier of the Notified Body)

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:

Date	Signature (certifier of the Notified Body)

Changzhou BomeDent Medical Technology Co., Ltd. 3204126053077

Hardcopy Original
TÜVR Shanghai
2024-04-22 Katrina