bredent GmbH & Co.KG
Weissenhorner Str. 2
D-89250 Senden

bredent

May 23, 2024

Extension of the validity of the
MDD certificate and the MDD declarations of conformity

With the confirmation letter in the appendix, the notified body (mdc medical device certification GmbH) confirms, that the validity of the MDD certificate (according to 93/42/EEC Annex II (without 4)) is **extended until December 31, 2028**.

As the validity of the MDD declarations of conformity is linked to the validity of the MDD certificate, the existing MDD declarations of conformity issued in 2021 will also remain valid until the expiry of the MDD certificate.

Senden, May 23, 2024

Olaf Glück, general manager

Appendix:
- D1020200077_CLMDD_sig_confirmation_letter_20240520
- Zertifikat bredent Richtlinie 93_42_EWG Anhang II englisch

bredent GmbH & Co. KG
Weissenhorner Str. 2
89250 Senden
Deutschland

Notified Body Confirmation Letter

Registration no.: D1020200077

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0483 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

bredent GmbH & Co. KG
Weissenhorner Str. 2
89250 Senden
Deutschland
SRN:DE-MF-000008124

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which a MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by Regulation (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Stuttgart, 2024-05-20

Head of Notified Body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

P010201 Dental implants and accessories			
++EBRE2bProthTiDD **++EBRE2bProthCAMTiU6** **++EBRE2bProthHPPC3** **++EBRE2bProthCAMHPPGH** **++EBRE2bProthSrewF4** **Abutmentsystems**	Class IIb	N/A	Certificate D1020200071, # 0483
Q010299 Devices for prosthetic dentistry - other			
++EBRE2aProthTiCS **++EBRE2aProthPOMCB** **++EBRE2aProthSetGH** **Abutmentsystems**	Class IIa	N/A	Certificate D1020200071, # 0483
Q010207 Dental impression devices for prosthetic ddentistry			
++EBRE2aScanA3 **Abutmentsystems**	Class IIa	N/A	Certificate D1020200071, # 0483
Q010205 Plastics and dental crowns			
++EBRE2aResinKFO49 **Dentaplast KFO**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aResinUniAE **uni.lign**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE1ResinCAM3F **breCAM.splint**	Class I (MDR), Class IIa (Directive)	N/A	Certificate D1020200071, # 0483
++EBRE2aProthGlazeA6 **visio.lign Glaze**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aOpaquer9P **Opaquer UV**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aProthLinerC4 **Prosthesis silicone**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aResinBioHPPNZ **++EBRE2aResinCAM2E** **BioHPP for2press, BioHPP, breCAM.BioHPP**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aProsthHIPC94 **breCAM.HIPC**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aResinCAM2E **breCAM.multiCOM**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aResinCAM2E **breCAM.monoCOM**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aResinTherm5K **Thermoplastic denture base resins**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aResinTopAS **top.lign**	Class IIa	N/A	Certificate D1020200071, # 0483

++EBRE2aProthCreaS4 **++EBRE2aVerbundBG** **visio.lign**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aResinVisio7X **novo.lign**	Class IIa	N/A	Certificate D1020200071, # 0483
Q010206 Dentures			
++EBRE2aResinVisio7X **++EBRE2aProsthNeoLign67** **neo.lign**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aProsthBioDentXZ **++EBRE2aProsthBioniCutTN** **++EBRE2aProsthBreFlexZ6** **Thermoplastic denture base resins**	Class IIa	N/A	Certificate D1020200071, # 0483
Q010280 Devices for prosthetic dentary - accessories			
++EBRE2aFlowSil4V **flow.sil**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aProthPOMCB **++EBRE2aProthTiCS** **++EBRE2aProthBioHPPZB** **++EBRE2aProthHLA6** **++EBRE2aProthScrewE5** **++EBRE2aProthBallFix6F** **++EBRE2aProthIRAM** **++EBRE2aProthSetGH** **Construction elements - attachments**	Class IIa	N/A	Certificate D1020200071, # 0483
Q010101 Dental restorative devices			
++EBRE2aVerbundBG **Paste-like denture base repair and expansion resins**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aVerbundFGP4X **FGP**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aVerbundPrimBE **Bonding agent**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aVerbundDTK5J **DTK**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aVerbundCeramAY **Metal-ceramic opaquer**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aPolyInk9N **Thermoplastic denture base resins**	Class IIa	N/A	Certificate D1020200071, # 0483
Q010699 Materials for the preparation of custom made devices - other			
++EBRE2aProthCAMCoCrD9 **++EBRE2aProthCAMTiT7** **++EBRE2aProthCastRX** **++EBRE2aProthSolderGM** **Dental alloys**	Class IIa	N/A	Certificate D1020200071, # 0483
++EBRE2aProthCAMZrUB **Dental ceramics**	Class IIa	N/A	Certificate D1020200071, # 0483

L159099 Dentistry instruments - other			
++EBRE2aInstrumenteS5 **Screwdriver**	Class IIa	N/A	Certificate D1020200071, # 0483

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
++EBRE1rInstrumenteCL **Screwdriver**	Class Ir	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-20	D1020200077	Initial

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

bredent GmbH & Co. KG
Weißenhorner Straße 2
89250 Senden
Germany

for the scope

dental products and products for epithetics
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2021-01-01
Valid until	2023-09-21
Registration no.	D1020200071
Report no.	P20-01828-190536
Stuttgart	2020-11-03

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1020200071 Date 2020-11-03 Page 1 of 1

Product category	Product	Class	Product code
dental products	alloys, dental	IIa	10-077
	elastomers, silicone rubber	IIa	11-394
	screws	IIa	16-055
	dental porcelains	IIa	16-187
	dental veneer	IIa	16-336
	adhesives, denture	IIa	16-388
	dental, hand instrument, other	IIa	16-667
	restorative materials, dental, crown and bridge	IIa	16-723
	restorative materials, dental, crown and bridge	IIb	16-723
	denture base resins	IIa	16-728
	denture base resins, heat-cured	IIa	16-729
	composite restorative material kits, dental, heat-cured	IIa	16-735
	dental precision attachment	IIa	17-113
	dental precision attachment	IIb	17-113
	teeth, dental prosthesis	IIa	17-114
	denture reliners, soft	IIa	17-610
	prostheses, dental, fixed	IIa	17-841
	dentures, partial	IIa	17-845
products for epithetics	prostheses, maxillofacial	IIa	13-162

Head of Certification Body

medical device certification mdc

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D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de