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

July 22, 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, July 22, 2024

Gerald Micko, general manager

Appendix:
- D1146000052_CLMDD_sig_confirmation letter_20240712
- Zertifikat medical Richtlinie 93_42_EWG Anhang II englisch

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

Notified Body Confirmation Letter

Registration no.: D1146000053

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 medical GmbH & Co. KG
Weissenhorner Str. 2
89250 Senden
Deutschland
SRN: DE-MF-000008125

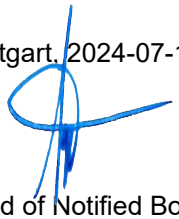
The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the 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, 2024-07-12



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:

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
P010201 Dental implants and accessories			
blueSKY implant	Class IIb implantable non-WET device	N/A	Certificate D1146000047, mdc 0483 Certificate D1146000052, mdc 0483
copaSKY implant			
narrowSKY implant			
SKY classic implant			
whiteSKY implant			
SKY prosthetic	Class IIb excluding Class IIb implantable non-WET		
	Class IIa		
miniSKY prosthetic	Class IIb excluding Class IIb implantable non-WET		
	Class IIa		
whiteSKY prosthetic	Class IIb excluding Class IIb implantable non-WET		
	Class IIa		
Z120615 Therapeutic Lasers			
HELBO Minilaser	Class IIb implantable non-WET device	N/A	Certificate D1146000047, mdc 0483 Certificate D1146000052, mdc 0483
HELBO TheraLite Laser	Class IIa (IIb MDD)		
HELBO Probe	Class IIa		
L159099 - Odontostomatology instruments - others			
Instruments	Class IIa	N/A	Certificate D1146000047, mdc 0483 Certificate D1146000052, mdc 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
L159099 - Odontostomatology instruments - others			
Instruments	Class I devices that qualify as re-usable surgical instruments	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
2024-07-12	D1146000053	Initial

mdc medical device certification GmbH
Kriegerstraße 6 | 70191 Stuttgart | Germany | www.mdc-ce.de