bredent medical

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

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

bredent medical GmbH & Co. KG
Weissenhorner Str. 2
89250 Senden | Germany
T: (+49) 0 73 09 / 872 - 600
F: (+49) 0 73 09 / 872 - 635
Gerald.Micko@bredent.com
www.bredent-medical.com

Ihr Zeichen	Ihre Nachricht	Unser Zeichen	Datum	Tel.-Durchwahl
		-	27.05.2024	(+49) 0 73 09 / 872 - 140

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending among others the Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	bredent medical GmbH & Co. KG
Manufacturer address and contact details	Weissenhorner Str. 2 89250 Senden Germany
Single Registration Number (SRN)	DE-MF-000008125

Notified body name	mdc medical device certification GmbH
Notified body number	0483
Directive Certificate number(s) to which this confirmation is made	D1146000047
Original expiry date as indicated on the Directive Certificate prior to the extension of the validit	30.10.2023
End date of extended validity/transition period	31.12.2028

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

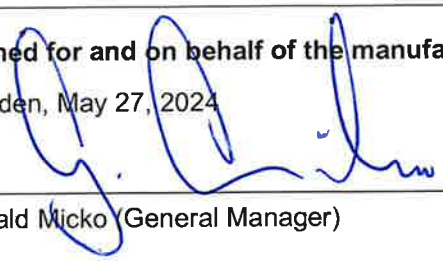
➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Signed for and on behalf of the manufacturer:

Senden, May 27, 2024



Gerald Micko (General Manager)

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

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
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
HELBO TheraLite Laser	Class IIa (IIb MDD)		
HELBO Probe	Class IIa		
L159099 - Odontostomatology instruments - others			
Instruments	Class IIa	N/A	Certificate D1146000047, mdc 0483
Instruments	Class I devices that qualify as re-usable surgical instruments	N/A	Certificate D1146000047, mdc 0483