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

September 12, 2023

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 May 26, 2024.

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, September 12, 2023

Olaf Glück, general manager

Appendix:
- D11460_C_SX_2023_08_22_Confirmation_letter_sig
- Zertifikat medical 93-42-EWG Anhang II englisch

mdc medical device certification GmbH · Kriegerstr. 6 · 70191 Stuttgart, Germany

bredent medical GmbH & Co. KG
Herrn Dimitrij Zeiger
Weißenhorner Straße 2
89250 Senden
Deutschland

Your signs, your letter dated	Our signs, our letter dated	Phone number	Date
	KKA-ASC	+49 711 253597-289	2023-08-22

Preliminary Confirmation Letter – validity of MDD certificates

Sehr geehrter Herr Zeiger,

mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany) has for the manufacturer:

bredent medical GmbH & Co. KG
Weißenhorner Straße 2
89250 Senden
Deutschland

issued the following certificate in accordance with Directive 93/42/EEC:

Certificate	Certificate registration No.	Certification	Date of issue	Expiry date
26171	D1146000047	Directive 93/42/EEC, Annex II, excluding 4	2021-05-20	2023-10-30

These certificates were valid as of 20 March 2023 and have not been withdrawn afterwards. In accordance with the requirements of Art. 120 (2), second subparagraph, first sentence of Regulation (EU) 2017/745 on Medical Devices (MDR), last amended by Regulation (EU) 2023/607 the above mentioned certificate shall remain valid until the date set out in Art 120 (3a) MDR.

This confirmation requires that the manufacturer complies with the requirements laid out in Art. 120 (3c) and (3d) MDR and will undergo further surveillance according to the rules of mdc medical device certification GmbH.

According to the requirements of Art. 120 (3a) MDR, the prerequisite for placing the concerned devices on the market is fulfilled until at least 26 May 2024, unless otherwise specified by the authorities or this letter is replaced by a contrary notification by mdc.

Kind regards,

mdc medical device certification GmbH

i. A. Katja Karich
(Team Management)

signiert von:
Katja Karich
am: 22.08.2023
mit:
digiSeal® by secrypt

ID: 10727– 002/04.2023
mdc medical device certification GmbH

Kriegerstraße 6
70191 Stuttgart, Germany

Phone +49 711 253597-0
Fax +49 711 253597-10
e-Mail mdc@mdc-ce.de
Web www.mdc-ce.de

General Manager
Chairman of the board
Registered office of the company
USt.IDNr DE812169576

Harald Rentschler
Dirk Palige
Stuttgart
AG Stuttgart HRB 21357

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

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

for the scope

dental and laser products
(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	2021-05-20
Valid until	2023-10-30
Registration no.	D1146000047
Report no.	P21-00413-200026
Stuttgart	2021-05-20

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

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Kriegerstraße 6
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Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Attachment of the certificate

No. D1146000047 Date 2021-05-20 Page 1 of 1

Product category	Product	Class	Product code
Dental products	Prosthesis implantation instruments, dental	IIa	17-992
	Prostheses, dental, implantable	IIb	16-744
	Dental precision attachment	IIa	17-113
	Dental precision attachment	IIb	17-113
	Burs, dental, steel	IIa	16-669
	Denture reliners, soft	IIa	17-610
	Burs, dental, zircon	IIa	10-521
Laser products	Laser, therapeutic	IIb	12-299
	Laser Delivery Systems, Waveguide	IIa	17-866

Head of Certification Body

medical device certification mdc

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