Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 021108 0031 Rev. 00

Manufacturer:

Dentsply De Trey GmbH
De-Trey-Strasse 1
78467 Konstanz
GERMANY

Facility(ies):

Dentsply De Trey GmbH
De-Trey-Strasse 1, 78467 Konstanz, GERMANY

Dentsply DeTrey GmbH Radolfzell Operation Center (ROC)
Güttinger Straße 35, 78315 Radolfzell, GERMANY

Product Category(ies): Products of class IIa:

Dental Restorative Materials (Conditioners, Adhesives, Filling Materials), Cements, Endodontic Filling Materials

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713167525

Valid from: 2019-12-01
Valid until: 2024-05-26

Date, 2019-11-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

M / 07 17

Dentsply DeTrey GmbH
Postfach 10 04 42
78404 Konstanz
GERMANY
Telefon +49 (0) 7531–583–0
Telefax +49 (0) 7531–583–104
E-Mail info.konstanz@dentsplysirona.com
www.dentsplysirona.com

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[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	Dentsply DeTrey GmbH
Manufacturer address and contact details	De-Trey-Str. 1 78467 Konstanz Germany
Single Registration Number (SRN) (if available)	DE-MF-00005905

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	TÜV SÜD Product Service GmbH ☒ See attached schedule
Notified body number (if applicable)	0123 ☒ See attached schedule

[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.

Dentsply DeTrey GmbH
De-Trey-Str. 1
78467 Konstanz
GERMANY

Geschäftsführung:
Jochen Dreymann • Marcel Dourbecker
Registergericht: Amtsgericht Freiburg, HRB 381533
UST-ID-Nr.: DE113524480
Steuer Nr.: 09080/00128

Commerzbank AG Frankfurt
Bankleitzahl 500 800 00
Kontonummer 00 920 708 01
BIC DRES DE FF
IBAN DE53 5008 0000 0092 0708 01

Dentsply Sirona

Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 021108 0031 Rev.00 ☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 ☒ See attached schedule
End date of extended validity/transition period	2028-12-31 ☒ See attached schedule

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/or*[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.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[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

Dentsply Sirona

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ 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.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ 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.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 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:

Choose one applicable statement:

- ☐ 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 substitutes 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.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ 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.

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

- The device(s) continue to comply with the AIMDD or 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.

Signed for and on behalf of the manufacturer:

Dentsply DeTrey GmbH

Konstanz, Germany, 2024-03-18

Dentsply DeTrey GmbH
De-Trey-Straße 1
78467 Konstanz
Germany

Grischka Friedrich

Senior Manager Quality Assurance & Regulatory Compliance
Grischka.Friedrich@dentsplysirona.com

Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
AH 26 / AH 26 silverfree Basic UDI-DI: ++D010EFM01PX	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
AH Plus, AH Plus Jet Basic UDI-DI: ++D010EFM02PZ	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
AH Plus Cleaner Basic UDI-DI: ++D010ACC03LG	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
AH Temp Basic UDI-DI: ++D010EFM03Q3	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Aquacem Basic UDI-DI: ++D010CEM01P2	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Ceram.X Spectra ST, TPH Spectra ST, Neo Spectra ST, ceram.x SphereTEC one, ceram.x duo Basic UDI-DI: ++D010FIM03R3	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Ceram.x Spectra ST flow, TPH Spectra ST flow, Neo Spectra ST fow Basic UDI-DI: ++D010FIM04R5	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
ChemFil Superior Basic UDI-DI: ++D010CEM06PC	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
ChemFil Tooth Cleanser Basic UDI-DI: ++D010ACC07LQ	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
DeTrey Conditioner 36 Basic UDI-DI: ++D010CON01RD	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
DeTrey Zinc Basic UDI-DI: ++D010CEM04P8	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Dyract Basic UDI-DI: ++D010FIM01QX	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Dyract eXtra, Dyract Posterior+, Dyract XP Basic UDI-DI: ++D010FIM02QZ	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A

Dyract flow Basic UDI-DI: ++D010FIM07RB	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
IRM Basic UDI-DI: ++D010CEM03P6	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Kalsogen Plus, Kalzinol Basic UDI-DI: ++D010CEM07PE	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
QuiXfil Basic UDI-DI: ++D010FIM09RF	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Poly-F, Poly-F Plus Basic UDI-DI: ++D010CEM05PA	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Prime&Bond active, Prime&Bond universal Basic UDI-DI: ++D010ADH02ME	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Prime&Bond NT, Spectrum bond Basic UDI-DI: ++D010ADH01MC	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Prime&Bond XP, prime&bond Etch&Rinse, Basic UDI-DI: ++D010ADH03MG	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A
Spectrum TPH3, Spectrum Basic UDI-DI: ++D010FIM06R9	G1 021108 0031 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	2028-12-31	N/A

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

Dentsply DeTrey GmbH
De-Trey-Strasse 1
78467 Konstanz
Germany

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
021108	713223912	+49 15161632139	-	2024-01-17	1 of 9
	Sascha Stumpp	sascha.stumpp@tuvsud.com			

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 021108 0034 Rev. 00

Reference: 713223912

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000005905

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

If 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;

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 021108 0034 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-01-17

TÜV SÜD Product Service GmbH
Medical and Health Services

Sascha Stumpp
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Jan 17, 2024 11:35 GMT+1)

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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
++D010ACC03LG	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010ACC07LQ	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010ADH01MC	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010ADH02ME	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
++D010ADH03MG	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010ADH05ML	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010CEM01P2	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010CEM02P4	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
++D010CEM03P6	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010CEM04P8	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010CEM05PA	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010CEM06PC	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
++D010CEM07PE	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010CON01RD	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010EFM01PX	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010EFM02PZ	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
++D010EFM03Q3	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010FIM01QX	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010FIM02QZ	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010FIM03R3	☐ Class III	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
++D010FIM04R5	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010FIM05R7	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010FIM06R9	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
++D010FIM07RB	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010FIM09RF	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123
++D010PFS01UN	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: G1 021108 0031 Rev. 00; 0123

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-01-17	713223912	Initial issue