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 095377 0008 Rev. 00

Manufacturer:

Prevest Denpro Limited
Export Promotion Industrial Park
(EPIP), Bari Brahamana
181133 JAMMU
INDIA

Product Category(ies): Dental Materials (Class IIa):
Restorative Materials (Filling, core build up and luting materials) Sealants, Liners and Base Materials, Adhesives, Cements and Filling Materials, Zinc Oxide-Eugenol Temporary Cements, Non-Eugenol Temporary Cements, Root Canal Sealing Materials, Endodontic Materials, Pulp Capping Materials, Varnishes and Desensitizers, Denture Base Polymers, Etching Materials, Auxiliary Materials for Dental Treatment.

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.: IND2019072

Valid from: 2020-04-23
Valid until: 2024-05-26

Date, 2020-04-23

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

Add value.
Inspire trust.

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Prevest Denpro Limited
Export Promotion Industrial Park (EPIP)
Unit II
Bari Brahmana
181133 JAMMU
INDIA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
95377	TPS3224_AR	ajit.kuchekar@tuvsud.com	--	2024-05-26	1 of 29

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 095377 0012 Rev. 00

Reference: **TPS3224_AR**

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: IN-MF-000011546

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.

- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable

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; 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.

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)

We reserve the right to invoice any issuance, 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 095377 0012 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-26

TÜV SÜD Product Service GmbH
Medical and Health Services

Ajit Kuchekar (PH) 2024.03.15
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Claus Matthias Mumme
Application Reviewer

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
Device :1 **Restorative Material (Magma -NT)** **Article No.** **20001** **20002** **20002-1** **20002-2** **20002-3** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate #G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :2 **Restorative Material (Magma -NT Unit Dose Compules** **Article No.** **20003** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :3 **Restorative Material (Fusion Universal)** **Article No.** **20004** **20005** **20005-1** **20006** **20006-1** **20006-2** **20006-3** **20007** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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
Device :4 **Restorative Material (Fusion Universal Unit Dose Compules)** **Article No.** **20007** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :5 **Restorative Material (Octolight)** **Article No.** **04-051** **04-052** **04-053** **04-054** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :6 **Restorative Materials (Fusion Flo)** **Article No.** **20008-1** **20008** **20008-2** **20009** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :7 **Restorative Materials (Octolight Flo)** **Article No.** **04-062** **04-063** **04-064**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or

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
Basic UDI : **D967RMTF0797**	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Restorative Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :8 **Restorative Materials (Fusion Flo SE)** **Article No.** **20008-3** **20008-4** **20008-5** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :9 **Restorative Materials (Self comp)** **Article No.** **20010** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :10 **Restorative Materials (Fusion Core DC Flo)** **Article No.** **20011** **20011-1** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :11	☐ Class III	☒ N/A	☒ Certification as follows:

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
Restorative Materials (PF Seal) **Article No.** **20012-1** **20012** **Basic UDI :** **D967RMTF0797**	☐ 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	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :12 **Restorative Materials (PF Seal SE)** **Article No.** **20012-2** **20012-3** **20012-4** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :13 **Restorative Materials (Fusion Ultra DC)** **Article No.** **30006** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :14 **Restorative Materials (Fusion Ultra D/C Universal)** **Article No.** **30007** **Basic UDI :**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or

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
D967RMTF0797	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Restorative Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :15 **Restorative Materials (Fusion Self Lute Intro Pack)** **Article No.** **30008** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :16 **Restorative Materials (Fusion Crysta Adhesive)** **Article No.** **10022** **10023** **Basic UDI :** **D967RMTF0797**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :17 **Sealent, liner and bases (Apacal Art)** **Article No.** **30001-1** **30001** **Basic UDI :** **D967SLTF089B**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Sealent, liner and bases	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :18	☐ Class III	☒ N/A	☒ Certification as follows:

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
Sealent, liner and bases (Fusion I Seal) **Article No.** **30002-1** **30002** **30003** **30003-1** **30003-2** **Basic UDI :** **D967SLTF089B**	☐ 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	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Sealent, liner and bases	Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :19 **Sealent, liner and bases (Cal LC)** **Article No.** **30004** **30005** **30005-1** **Basic UDI :** **D967SLTF089B**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :20 **Adhesive (Fusion Bond 7)** **Article No.** **10001** **10002** **Basic UDI :** **D967ADTF09X8**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :21 **Adhesive (Fusion Self Etch Bond)** **Article No.** **10001-1** **10002-1** **Basic UDI :** **D967ADTF09X8**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had

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		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :22 **Adhesive (Fusion Bond 5)** **Article No.** **10003** **10004** **Basic UDI :** **D967ADTF09X8**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :23 **Adhesive (Fusion Total Etch Bond)** **Article No.** **10003-1** **10004-1** **Basic UDI :** **D967ADTF09X8**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :24 **Adhesive (Fusion Bond DC)** **Article No.** **10005** **Basic UDI :** **D967ADTF09X8**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :25 **Adhesive (Renew MDP)** **Article No.**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate

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
10016 **Basic UDI :** **D967ADTF09X8**	☐ 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	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :26 **Adhesive (Renew Universal)** **Article No.** **10017** **10018** **10019** **Basic UDI :** **D967ADTF09X8**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :27 **Adhesive (Fusion Crysta Adhesive Primer)** **Article No.** **10021** **Basic UDI :** **D967ADTF09X8**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :28 **Adhesive (Fusion Crysta MDP Orthodontic Adhesive)** **Article No.** **10024** **Basic UDI :** **D967ADTF09X8**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

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
			Evidence #2; CA#
Device :29 **Adhesive (Fusion Crysta Regular Orthodontic Adhesive)** **Article No.** **10024-1** **Basic UDI :** **D967ADTF09X8**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :30 **Dental cement (Micron Silver)** **Article No.** **30009** **Basic UDI :** **D967DCTF10XM**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :31 **Dental cement (Micron Bioactive)** **Article No.** **30009-1** **Basic UDI :** **D967DCTF10XM**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :32 **Dental cement (Micron Superior)** **Article No.** **30010**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or

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
Basic UDI : **D967DCTF10XM**	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number: Dental Cement	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :33 **Dental cement (Micron Superior Capsules)** **Article No.** **30010-3** **Basic UDI :** **D967DCTF10XM**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :34 **Dental cement (Micron Luting)** **Article No.** **30011** **Basic UDI :** **D967DCTF10XM**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :35 **Dental cement (Poly Zinc +)** **Article No.** **30012** **30013** **Basic UDI :** **D967DCTF10XM**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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
Device :36 **Dental cement** **(Zinc F+)** **Article No.** **30014** **30014-1** **Basic UDI :** **D967DCTF10XM**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :37 **Dental cement** **(Crysta Restorative)** **Article No.** **30017** **Basic UDI :** **D967DCTF10XM**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :38 **Dental cement** **(Crysta Luting)** **Article No.** **30018** **Basic UDI :** **D967DCTF10XM**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :39 **Dental cement** **(Crysta Boactive)** **Article No.** **30019** **Basic UDI :**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or

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
D967DCTF10XM	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Dental Cement	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :40 **Dental cement** **(Crysta Silver)** **Article No.** **30020** **Basic UDI :** **D967DCTF10XM**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :41 **Temporary Filling Material (Orafil G)** **Article No.** **11001** **Basic UDI :** **D967TMTF119Q**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Temporary Filling Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :42 **Temporary Filling Material (Orafil Plus)** **Article No.** **11002** **Basic UDI :** **D967TMTF119Q**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Temporary Filling Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :43	☐ Class III	☒ N/A	☒ Certification as follows:

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
Temporary Filling Material (Oratemp NE) **Article No.** **11003** **11004** **Basic UDI :** **D967TMTF119Q**	☐ 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	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Temporary Filling Material	Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :44 **Temporary Filling Material (Orafil LC)** **Article No.** **11002-1** **Basic UDI :** **D967TMTF119Q**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Temporary Filling Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :45 **Temporary Filling Material (Oratemp C&B)** **Article No.** **11005** **Basic UDI :** **D967TMTF119Q**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Temporary Filling Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :46 **Temporary Filling Material (Zinc Oxide Powder)** **Article No.** **40028** **Basic UDI :** **D967TMTF119Q**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Temporary Filling Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had

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		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :47 **Root Canal Sealing Material (GuttaFill BA)** **Article No.** **40001** **Basic UDI :** **D967ESTF015L**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Root Canal Sealing Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :48 **Root Canal Sealing Material (Eposeal)** **Article No.** **40013** **40013-1** **Basic UDI :** **D967ESTF015L**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Root Canal Sealing Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :49 **Root Canal Sealing Material (Zical)** **Article No.** **40010** **40011** **Basic UDI :** **D967ESTF015L**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Root Canal Sealing Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :50 **Root Canal Sealing Material (Endoseal Plus)**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate

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
Article No. **40012** **Basic UDI :** **D967ESTF015L**	☐ 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	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Root Canal Sealing Material	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :51 **Root Canal Sealing Material (MTA Plus)** **Article No.** **40024** **40025** **40032** **Basic UDI :** **D967ESTF015L**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Root Canal Sealing Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :52 **Root Canal Sealing Material (MTA Plus Aqua)** **Article No.** **40024-1** **40053** **Basic UDI :** **D967ESTF015L**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Root Canal Sealing Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :53 **Root Canal Sealing Material (Cerafill RCS)** **Article No.** **40037** **40037-1** **40037-2** **40057** **Basic UDI :** **D967ESTF015L**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Root Canal Sealing Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

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
			Evidence #2; CA#
Device :54 **Endodontic Material (Dolo EDTA Gel)** **Article No.** **40002** **40002-1** **40003** **Basic UDI :** **D967EMTF023L**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Endodontric Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :55 **Endodontic Material (EDTA Solution)** **Article No.** **40004** **40004-1** **Basic UDI :** **D967EMTF023L**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Endodontric Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :56 **Endodontic Material (EDTA Plus)** **Article No.** **02-032pulp** **Basic UDI :** **D967EMTF023L**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Endodontric Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :57 **Endodontic Material (Carvene)** **Article No.** **40030** **Basic UDI :**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or

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
D967EMTF023L	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number: Endodontric Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :58 **Pulp capping material (Calcigel)** **Article No.** **40007** **40007-1** **40007-2** **40008** **Basic UDI :** **D967PCTF044R**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Pulp cappingMaterial	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :59 **Pulp capping material (Pulp X)** **Article No.** **40021** **40022** **40022-1** **Basic UDI :** **D967PCTF044R**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Pulp capping Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :60 **Pulp capping material (Octocanal)** **Article No.** **02-003** **Basic UDI :** **D967PCTF044R**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Pulp capping Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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
Device :61 **Pulp capping material (Calcium Hydroxide Powder)** **Article No.** **40029** **Basic UDI :** **D967PCTF044R**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Pulp capping Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :62 **Desensitizer & Varnishes (Fusion Nano Coat)** **Article No.** **20013** **Basic UDI :** **D967DVTF126D**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Desensitizer & Varnishes	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :63 **Desensitizer & Varnishes (Copal F)** **Article No.** **40027** **Basic UDI :** **D967DVTF126D**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Desensitizer & Varnishes	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :64 **Desensitizer & Varnishes (FlouroDip Bioactive)** **Article No.** **80001** **80001-2** **80001-3** **80001-4**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or

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
Basic UDI : **D967DVTF126D**	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Desensitizer & Varnishes	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :65 **Desensitizer & Varnishes (Shield Activ)** **Article No.** **80003** **Basic UDI :** **D967DVTF126D**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Desensitizer & Varnishes	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :66 **Desensitizer & Varnishes (BioEnamel Gel)** **Article No.** **90012** **(BioEnamel Gel)** **90017**(KLAR remineral) **90018** **(KLAR KID remineral)** **Basic UDI :** **D967DVTF126D**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Desensitizer & Varnishes	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :67 **Denture Base Polymers (Hiflex RR)** **Article No.** **15001** **15002** **15003** **Basic UDI :** **D967DBTF13XG**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Denture Base Polymers	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :68	☐ Class III	☒ N/A	☒ Certification as follows:

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
Denture Base Polymers (Hiflex H) **Article No.** **15004** **15005** **15006** **Basic UDI :** **D967DBTF13XG**	☐ 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	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Denture Base Polymers	Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :69 **Etching Materials (Actino Gel)** **Article No.** **10006-1** **10006-2** **10006-3** **10006-5** **10006** **10007** **10008** **Basic UDI :** **D967ETTF1468**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Etching Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :70 **Etching Materials (Actino Liquid)** **Article No.** **10009** **Basic UDI :** **D967ETTF1468**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Etching Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :71 **Etching Materials (Microgel SF)** **Article No.** **10010** **10011** **Basic UDI :** **D967ETTF1468**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Etching Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had

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		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :72 **Etching Materials (Cera Etch)** **Article No.** **10012** **10013** **Basic UDI :** **D967ETTF1468**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Etching Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :73 **Auxiliary Dental Materials(Silane X)** **Article No.** **10014** **10015** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :74 **Auxiliary Dental Materials(Micron Dentin Conditioner)** **Article No.** **30010-1** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :75 **Auxiliary Dental Materials(Ultra Dry)**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 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
Article No. **40033** **40034** **Basic UDI :** **D967AMTF0322**	☐ 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	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :76 **Auxiliary Dental Materials(EpoSolv)** **Article No.** **40035** **Basic UDI** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :77 **Auxiliary Dental Materials(Platina Hi Gloss)** **Article No.** **50001** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :78 **Auxiliary Dental Materials(ACE)** **Article No.** **50002** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#

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
			Evidence #2; CA#
Device :79 **Auxiliary Dental Materials(Spectra -Fresh Mint, Orange , Pineapple, Strawberry, and fresh Fruit Prophylaxis Paste)** **Article No.** **50005** **50005-1** **50006** **50007** **50008** **50009** **50010** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :80 **Auxiliary Dental Materials(Reveal)** **Article No.** **80002** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :81 **Auxiliary Dental Materials(Gingiva Shield VLC)** **Article No.** **90010** **90011** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :82 **Auxiliary Dental Materials(Silano-X)** **Article No.**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate

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
04-021 **Basic UDI :** **D967AMTF0322**	☐ 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	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :83 **Auxiliary Dental Materials (Crysta Dentin Conditioner)** **Article No.** **30021** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :84 **Auxiliary Dental Materials (Octoop)** **Article No.** **04-022** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :85 **Auxiliary Dental Materials (White Care Barrier Gingivale)** **Article No.** **WCBGI** **Basic UDI :** **D967AMTF0322**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Auxiliary Dental Materials	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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
Device :86 **Zinc Oxide Eugenol Temporary Filling Material (Zinconol)** **Article No.** **30015** **30015-1** **30016** **Basic UDI :** **D967ZETF069M**	☐ 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 or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Zinc Oxide Eugenol Temporary Filling Material	☒ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 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
Not Applicable	☒	☒	☒

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-26	TPS3224_AR	Initial issue