





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



Add value. Inspire trust.

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

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

Your reference/letter of 95377

Our reference/name TPS3224_AR Tel. extension/Email ajit.kuchekar@tuvsud.com

Fax extension

Date 2024-05-26

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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 <u>not</u> 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

TÜV SÜD Product Service GmbH Medical and Health Services

Ajit Kuchekar (PH) 2024.03.15

Conformity Assessment Responsible (CARE)

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 applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device :1	☐ Class III	⊠ N/A	☐ Certification as follows:
Restorative Material (Magma -NT)	☐ Class IIb implantable (non-exempted)	or	Certificate #G10953770008, Rev.00; NB# 0123
Article No. 20001	☐ Class IIb / Class IIb implantable (exempted) ☑ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	Certificate or
20002	☐ Class I devices in sterile	Individual Article number:	
20002-1	condition	Restorative Material	☐ Evidence that a competent au-
20002-2 20002-3	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
Basic UDI:	tom-made-device		Evidence #2; CA#
D967RMTF0797			,
	☐ Class III	⊠ N/A	☑ Certification as follows:
Device :2	☐ Class IIb implantable		Certificate # G10953770008,
Restorative Material	(non-exempted)	or	Rev.00; NB# 0123 Certificate
(Magma -NT Unit Dose Compules	☐ Class IIb / Class IIb implantable (exempted)		Certificate
Computes	⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
Article No.	☐ Class I devices in sterile	Individual Article number:	oi e
20003	condition	Restorative Material	☐ Evidence that a competent au-
2000	☐ Class I devices with meas-	Restorative Material	thority of a Member State had
Basic UDI :	uring function		granted acc. MDR, Art.59 (1) or
D967RMTF0797	☐ Class III implantable cus-		Art.97 (1)
	tom-made-device		Evidence #1; CA#
			Evidence #2; CA#
Device :3	☐ Class III	⊠ N/A	M Contification of 5-11
Restorative Material (Fu-		⊠ N/A	☐ Certification as follows: Certificate # G10953770008,
sion Universal)	☐ Class IIb implantable (non-exempted)	or	Rev.00; NB# 0123
Article No.	Class IIb / Class IIb im-		Certificate
20004	plantable (exempted)	☐ Identification of the correspond-	
20004	⊠ Class IIa	ing device under MDD/AIMDD	or
20005	☐ Class I devices in sterile condition	Individual Article number:	☐ Evidence that a competent au-
20005-1	☐ Class I devices with meas-	Restorative Material	thority of a Member State had
20006-1	uring function		granted acc. MDR, Art.59 (1) or
20006-2	☐ Class III implantable cus-		Art.97 (1)
20006-3	tom-made-device		Evidence #1; CA#
20007			Evidence #2; CA#
Basic UDI :			
D967RMTF0797			



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	□ Class III	⊠ N/A	□ Certification as follows:
	☐ Class IIb implantable	KN IN/A	Certificate # G10953770008,
Device :4	(non-exempted)	or	Rev.00; NB# 0123
Restorative Material (Fu-	☐ Class IIb / Class IIb im-		Certificate
sion Universal Unit Dose Compules)	plantable (exempted)	☐ Identification of the correspond-	
Computes	⊠ Class IIa	ing device under MDD/AIMDD	or
Article No.	☐ Class I devices in sterile	Individual Article number:	
20007	condition	Restorative Material	☐ Evidence that a competent authority of a Member State had
Basic UDI :	☐ Class I devices with measuring function		granted acc. MDR, Art.59 (1) or
D967RMTF0797	☐ Class III implantable cus-		Art.97 (1)
	tom-made-device		Evidence #1; CA#
			Evidence #2; CA#
Device :5	☐ Class III	⊠ N/A	☐ Certification as follows:
Restorative Material (Octolight)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
	☐ Class IIb / Class IIb im-		Certificate
Article No.	plantable (exempted)	☐ Identification of the correspond-	
04-051	⊠ Class IIa 	ing device under MDD/AIMDD	or
04-052	☐ Class I devices in sterile condition	Individual Article number:	
04-053 04-054	☐ Class I devices with measuring function	Restorative Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or
Basic UDI :	☐ Class III implantable cus-		Art.97 (1)
D967RMTF0797	tom-made-device		Evidence #1; CA# Evidence #2; CA#
230711111110737			Evidence #2, CA#
	☐ Class III	⊠ N/A	☐ Certification as follows:
Device :6	☐ Class IIb implantable (non-exempted)		Certificate # G10953770008, Rev.00; NB# 0123
Restorative Materials (Fusion Flo)	Class IIb / Class IIb im-	or	Certificate
,	plantable (exempted)	☐ Identification of the correspond-	
Article No.	⊠ Class IIa	ing device under MDD/AIMDD	or
20008-1 20008	☐ Class I devices in sterile	Individual Article number:	
20008-2	condition	Restorative Material	☐ Evidence that a competent au-
20009	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or
Basic UDI: D967RMTF0797	☐ Class III implantable cus-		Art.97 (1) Evidence #1; CA#
D30/NIVITEU/3/	tom-made-device		Evidence #1; CA# Evidence #2; CA#
			Lvidence π2, CAπ
Davigo •7	□ Class III	⊠ N/A	☐ Certification as follows:
Device :7 Restorative Materials (Octolight Flo)	☐ Class IIb implantable (non-exempted)		Certificate # G10953770008, Rev.00; NB# 0123
····giit i ivj	☐ Class IIb / Class IIb im-	or	Certificate
Article No.	plantable (exempted)	☐ Identification of the correspond-	
04-062	⊠ Class IIa	ing device under MDD/AIMDD	or
04-063 04-064	☐ Class I devices in sterile condition	Individual Article number:	



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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	□ Class III	⊠ N/A	☐ Certification as follows:
Restorative Materials (Fusion Flo SE)	Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb implantable (exempted)	☐ Identification of the correspond-	
20008-3 20008-4 20008-5	⊠ Class IIa □ Class I devices in sterile	ing device under MDD/AIMDD Individual Article number:	or
Basic UDI : D967RMTF0797	condition ☐ Class I devices with measuring function ☐ Class III implantable cus-	Restorative Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	tom-made-device		Evidence #1; CA# Evidence #2; CA#
			_
Device :9	☐ Class III☐ Class IIb implantable	⊠ N/A	☐ Certification as follows: Certificate # G10953770008,
Restorative Materials (Self comp)	(non-exempted) ☐ Class IIb / Class IIb im-	or	Rev.00; NB# 0123 Certificate
Article No. 20010	plantable (exempted) ⊠ Class IIa □ Class I devices in sterile	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	or
Basic UDI : D967RMTF0797	condition ☐ Class I devices with measuring function ☐ Class III implantable cus-	Restorative Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	tom-made-device		Evidence #1; CA#
			Evidence #2; CA#
Device :10	☐ Class III	⊠ N/A	☐ Certification as follows:
Restorative Materials (Fusion Core DC Flo)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 20011	☐ Class IIb / Class IIb implantable (exempted)	☐ Identification of the correspond-	Certificate
20011-1	⊠ Class IIa □ Class I devices in sterile	ing device under MDD/AIMDD Individual Article number:	or
Basic UDI : D967RMTF0797	condition ☐ Class I devices with measuring function ☐ Class III implantable cus-	Restorative Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	tom-made-device		Evidence #1; CA# Evidence #2; CA#
Device :11	☐ Class III	⊠ N/A	⊠ Certification as follows:



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Restorative Materials (PF Seal)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 20012-1	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Certificate or
20012 Basic UDI: 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 :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		☐ 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 applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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	☐ Class III	⊠ N/A	☐ Certification as follows:
Restorative Materials (Fusion Self Lute Intro Pack) Article No.	☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	or ☐ Identification of the correspond-	Certificate # G10953770008, Rev.00; NB# 0123 Certificate
30008	☐ Class IIa	ing device under MDD/AIMDD	or
D . IDI	☐ Class I devices in sterile	Individual Article number:	
Basic UDI : D967RMTF0797	condition ☐ Class I devices with measuring function ☐ Class III implantable cus-	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#
	tom-made-device		Evidence #1; CA# Evidence #2; CA#
			Evidence #2; CA#
Device :16	☐ Class III	⊠ N/A	☐ Certification as follows:
Restorative Materials (Fusion Crysta Adhesive)	☐ Class III ☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 10022 10023 Basic UDI: D967RMTF0797	☐ Class IIb / Class IIb implantable (exempted) ☑ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with meas-	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	or □ Evidence that a competent authority of a Member State had
	uring function ☐ Class III implantable custom-made-device		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.	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb im-	⊠ N/A or	☐ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate
30001-1 30001	plantable (exempted) ⊠ Class IIa □ Class I devices in sterile condition	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	or
Basic UDI : D967SLTF089B	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Sealent, liner and bases	☐ 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 applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 30002-1 30002 30003 30003-1 30003-2	☐ Class IIb / Class IIb implantable (exempted) ☑ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with meas-	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Sealent, liner and bases	or □ Evidence that a competent authority of a Member State had
Basic UDI : D967SLTF089B	uring function ☐ Class III implantable custom-made-device		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.	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)		☑ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate
30004 30005 30005-1 Basic UDI : D967SLTF089B	□ Class IIa □ Class I devices in sterile condition □ Class I devices with measuring function	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Restorative Material	or □ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA# Evidence #2; CA#
Device :20 Adhesive (Fusion Bond 7)	☐ Class III ☐ Class IIb implantable (non-exempted)	⊠ N/A or	☑ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate
Article No. 10001 10002	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhe-	or
Basic UDI : D967ADTF09X8	condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	sive	☐ 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	☐ Class III	⊠ N/A	☐ Certification as follows:
Adhesive (Fusion Self Etch Bond)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 10001-1 10002-1	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhe-	or
Basic UDI : D967ADTF09X8	condition	sive	☐ Evidence that a competent authority of a Member State had



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function		granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device :22	☐ Class III	⊠ N/A	☐ Certification as follows:
Adhesive	☐ Class IIb implantable		Certificate # G10953770008,
(Fusion Bond 5)	(non-exempted)	or	Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-		Certificate
10003	plantable (exempted)	☐ Identification of the correspond-	
10004	⊠ Class IIa	ing device under MDD/AIMDD	or
Basic UDI :	☐ Class I devices in sterile condition	Individual Article number: Adhesive	☐ Evidence that a competent au-
D967ADTF09X8	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
			2, 611
Device :23	☐ Class III	⊠ N/A	☑ Certification as follows:
Adhesive (Fusion Total Etch Bond)	☐ Class IIb implantable		Certificate # G10953770008,
Etth Bond)	(non-exempted) ☐ Class IIb / Class IIb im-	or	Rev.00; NB# 0123 Certificate
Article No.	plantable (exempted)	\[\tau_4 \cdot \c	Certificate
10003-1 10004-1	⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
	☐ Class I devices in sterile	Individual Article number:Adhe-	
Basic UDI:	condition	sive	☐ Evidence that a competent au-
D967ADTF09X8	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device :24	☐ Class III	⊠ N/A	☐ Certification as follows:
Adhesive (Fusion Bond DC)	☐ Class IIb implantable		Certificate # G10953770008, Rev.00; NB# 0123
	(non-exempted) ☐ Class IIb / Class IIb im-	or	Certificate
Article No.	plantable (exempted)	☐ Identification of the common and	
10005	⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
Basic UDI :	☐ Class I devices in sterile	Individual Article number:Adhe-	
D967ADTF09X8	condition	sive	☐ Evidence that a competent au-
	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
	ioni made device		Evidence #2; CA#
Device :25	☐ Class III	⊠ N/A	☑ Certification as follows:
Adhesive (Renew MDP)	☐ Class IIb implantable (non-exempted)		Certificate # G10953770008, Rev.00; NB# 0123
Article No.	(non exempted)	or	Certificate



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer 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 Devidence 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	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:Adhesive	☐ 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		☑ 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		□ 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 applica- tion)	MDR Device classification (as proposed by the manu- facturer 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	☐ Class III	⊠ N/A	☐ Certification as follows:
Adhesive (Fusion Crysta Regular Orthodontic Adhesive)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb implantable (exempted)	☐ Identification of the correspond-	Certificate
10024-1	☑ Class IIa☑ Class I devices in sterile	ing device under MDD/AIMDD Individual Article number: Adhe-	or
Basic UDI:	condition	sive	☐ Evidence that a competent au-
D967ADTF09X8	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
			Evidence #2; CA#
Device :30	☐ Class III	⊠ N/A	☐ Certification as follows:
Dental cement (Micron Silver)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-		Certificate
30009	plantable (exempted) ⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
Basic UDI:	☐ Class I devices in sterile	Individual Article number:	
D967DCTF10XM	☐ Class I devices with measuring function	Dental Cement	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device :31	☐ Class III	⊠ N/A	☐ Certification as follows:
Dental cement (Micron Bioactive)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-		Certificate
30009-1	plantable (exempted) ⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
Basic UDI:	☐ Class I devices in sterile condition	Individual Article number:	
D967DCTF10XM	☐ Class I devices with measuring function	Dental Cement	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
			,
Device :32	☐ Class III	⊠ N/A	☐ Certification as follows:
Dental cement (Micron Superior)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 30010	☐ Class IIb / Class IIb implantable (exempted)	☐ Identification of the correspond-	Certificate
30010	⊠ Class IIa	ing device under MDD/AIMDD	or



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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	□ 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		☐ 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		☐ 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) Device :36 Dental cement (Zinc F+) Article No. 30014 30014-1 Basic UDI: D967DCTF10XM	MDR Device classification (as proposed by the manufacturer and verified during application review) Class III Class III 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	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device N/A N/A or □ Identification of the corresponding device under MDD/AIMDD Individual Article number: Dental Cement	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification ☑ 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#
			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		☐ 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#
D : 20		57.31/4	M.C. J.C. J. C.H.
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	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		 ☑ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate or



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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	□ Class III	N/A	☐ Certification as follows:
Dental cement		⊠ IV/A	Certificate # G10953770008,
(Crysta Silver)	Class IIb implantable (non-exempted)	or	Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb implantable (exempted)		Certificate
30020	□ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
000 <u>4</u> 0	☐ Class I devices in sterile	Individual Article number:	
Basic UDI : D967DCTF10XM	condition Class I devices with measuring function Class III implantable cus-	Dental Cement	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	tom-made-device		Evidence #1; CA#
			Evidence #2; CA#
Device :41		N N/A	M.C. (C. 1)
Temporary Filling Material (Orafil G)	☐ Class III☐ Class IIb implantable	⊠ N/A	☐ Certification as follows: Certificate # G10953770008,
Hai (Oralli G)	(non-exempted)	or	Rev.00; NB# 0123 Certificate
Article No.	☐ Class IIb / Class IIb implantable (exempted)		Certificate
11001	⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
Basic UDI:	☐ Class I devices in sterile	Individual Article number:	
D967TMTF119Q	condition ☐ Class I devices with measuring function ☐ Class III implantable cus-	Temporary Filling Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1: CA#
	tom-made-device		Evidence #2: CA#
Device :42	☐ Class III	N/A	☐ Certification as follows:
Temporary Filling Material (Orafil Plus)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb implantable (exempted)	☐ Identification of the correspond-	Certificate
11002	⊠ Class IIa	ing device under MDD/AIMDD	or
Basic UDI:	☐ Class I devices in sterile	Individual Article number:	
D967TMTF119Q	condition ☐ Class I devices with measuring function ☐ Class III implantable cus-	Temporary Filling Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	tom-made-device		Evidence #1; CA#
			Evidence #2; CA#
Device :43	☐ Class III	⊠ N/A	□ Certification as follows:



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer 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)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 11003 11004 Basic UDI: D967TMTF119Q	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Temporary Filling Material	or Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		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	□ 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		☐ 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		□ 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 applica- tion)	MDR Device classification (as proposed by the manu- facturer 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		granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device :47	□ Class III	⊠ N/A	□ Certification as follows:
Root Canal Sealing Mate-	☐ Class IIb implantable		Certificate # G10953770008,
rial (GuttaFill BA)	(non-exempted)	or	Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-		Certificate
40001	plantable (exempted)	☐ Identification of the correspond-	
	⊠ Class IIa	ing device under MDD/AIMDD	or
Basic UDI:	☐ Class I devices in sterile	Individual Article number:	
D967ESTF015L	condition ☐ Class I devices with measuring function	Root Canal Sealing Material	Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or
	☐ Class III implantable cus-		Art.97 (1) Evidence #1; CA#
	tom-made-device		Evidence #1; CA# Evidence #2; CA#
			Evidence #2, CA#
Device :48	☐ Class III	⊠ N/A	☐ Certification as follows:
Root Canal Sealing Material (Eposeal)	☐ Class IIb implantable		Certificate # G10953770008, Rev.00; NB# 0123
,	(non-exempted) □ Class IIb / Class IIb im-	or	Certificate
Article No.	plantable (exempted)	☐ Identification of the correspond-	
40013 40013-1	⊠ Class IIa	ing device under MDD/AIMDD	or
Basic UDI :	☐ Class I devices in sterile condition	Individual Article number:	
D967ESTF015L	☐ Class I devices with meas-	Root Canal Sealing Material	☐ Evidence that a competent authority of a Member State had
	uring function		granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
	lean made device		Evidence #2; CA#
Device :49	□ Class III	⊠ N/A	⊠ Certification as follows:
Root Canal Sealing Material (Zical)	☐ Class IIb implantable (non-exempted)		Certificate # G10953770008, Rev.00; NB# 0123
	□ Class IIb / Class IIb im-	or	Certificate
Article No.	plantable (exempted)	☐ Identification of the correspond-	
40010 40011	⊠ Class IIa	ing device under MDD/AIMDD	or
	☐ Class I devices in sterile	Individual Article number:	
Basic UDI:	condition	Root Canal Sealing Material	☐ Evidence that a competent au-
D967ESTF015L	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device :50	☐ Class III	⊠ N/A	☑ Certification as follows:
Root Canal Sealing Material (Endoseal Plus)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
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Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer 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 Device:51 Root Canal Sealing Material (MTA Plus)	☐ 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 ☐ Class III ☐ Class III ☐ Class III implantable (non-exempted)	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Root Canal Sealing Material ☑ N/A	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# □ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123
Article No. 40024 40025 40032 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 :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	□ 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		☐ 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 applica- tion)	MDR Device classification (as proposed by the manu- facturer 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	☐ Class III	⊠ N/A	☑ Certification as follows:
Endodontic Material (Dolo EDTA Gel)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 40002	☐ Class IIb / Class IIb implantable (exempted)	☐ Identification of the correspond-	Certificate
40002-1 40003	⊠ Class IIa □ Class I devices in sterile	ing device under MDD/AIMDD Individual Article number:	or
Basic UDI : D967EMTF023L	condition ☐ Class I devices with measuring function ☐ Class III implantable cus-	Endodontric Material	□ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	tom-made-device		Evidence #1; CA# Evidence #2; CA#
			L vidence π2, C/Aπ
Device :55	☐ Class III	⊠ N/A	☐ Certification as follows:
Endodontic Material (EDTA Solution)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-		Certificate
40004	plantable (exempted)	☐ Identification of the correspond-	
40004-1	⊠ Class IIa	ing device under MDD/AIMDD	or
	☐ Class I devices in sterile	Individual Article number:	
Basic UDI : D967EMTF023L	condition Class I devices with measuring function	Endodontric Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
			2
Device :56	☐ Class III	⊠ N/A	⊠ Certification as follows:
Endodontic Material (EDTA Plus)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-		Certificate
02-032pulp	plantable (exempted) ⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
Basic UDI : 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 :57	☐ Class III	⊠ N/A	☑ Certification as follows:
Endodontic Material (Carvene)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 40030	☐ Class IIb / Class IIb implantable (exempted)	☐ Identification of the correspond-	Certificate
Basic UDI :	⊠ Class IIa	ing device under MDD/AIMDD	or



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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)	☐ Class III ☐ Class IIb implantable (non-exempted)	⊠ N/A or	☐ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate
Article No. 40007 40007-1 40007-2 40008 Basic UDI: D967PCTF044R	☐ 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: Pulp cappingMaterial	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		☐ 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 applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device :61	☐ Class III	⊠ N/A	☐ Certification as follows:
Pulp capping material (Calcium Hydroxide Pow-	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
der)	☐ Class IIb / Class IIb im-		Certificate
Article No.	plantable (exempted)	☐ Identification of the correspond-	
40029	⊠ Class IIa	ing device under MDD/AIMDD	or
Basic UDI :	☐ Class I devices in sterile condition	Individual Article number:	
D967PCTF044R	☐ Class I devices with measuring function	Pulp capping Material	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device :62	☐ Class III	⊠ N/A	☑ Certification as follows:
Desensitizer & Varnishes (Fusion Nano Coat)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-		Certificate
20013	plantable (exempted)	☐ Identification of the correspond-	
Basic UDI :	⊠ Class IIa	ing device under MDD/AIMDD	or
D967DVTF126D	☐ Class I devices in sterile condition	Individual Article number:	☐ Evidence that a competent au-
270.2 (11 1202	☐ Class I devices with measuring function	Desensitizer & Varnishes	thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device :63	☐ Class III	⊠ N/A	☐ Certification as follows:
Desensitizer & Varnishes (Copal F)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-		Certificate
40027	plantable (exempted)	☐ Identification of the correspond-	
Basic UDI :	⊠ Class IIa	ing device under MDD/AIMDD	or
D967DVTF126D	☐ Class I devices in sterile condition	Individual Article number:	D Evidence that a commetent ov
D/0/DV 11120D	☐ Class I devices with measuring function	Desensitizer & Varnishes	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
			Evidence #2; CA#
Danier (4		N/A	M.C. C.C. C.Y.
Device :64 Desensitizer & Varnishes	☐ Class III	⊠ N/A	☐ Certification as follows:
(FlouroDip Bioactive)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123 Certificate
Article No.	☐ Class IIb / Class IIb implantable (exempted)		Cerunicate
80001 80001-2 80001-3	⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
80001-3 80001-4		Individual Article number:	



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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	☐ Class III	N/A	☐ Certification as follows:
Desensitizer & Varnishes (Shield Activ)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 80003 Basic UDI :	☐ Class IIb / Class IIb implantable (exempted) ☑ Class IIa ☐ Class I devices in sterile	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Certificate or
D967DVTF126D	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 :66	□ Class III	⊠ N/A	☐ Certification as follows:
Desensitizer & Varnishes (BioEnamel Gel)	☐ Class III ☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 90012 (BioEnamel Gel) 90017 (KLAR remineral) 90018 (KLAR KID remineral) Basic UDI: D967DVTF126D	☐ 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: Desensitizer & Varnishes	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	☐ 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
15002 15003 Basic UDI : D967DBTF13XG	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable cus-	Individual Article number: Denture Base Polymers	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#
Device :68	tom-made-device	⊠ N/A	Evidence #2; CA#



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer 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	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
	☐ Class III implantable custom-made-device		Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device :69 Etching Materials (Actino Gel)	☐ Class III ☐ Class IIb implantable (non-exempted)	⊠ N/A	☑ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123
Article No. 10006-1 10006-2 10006-3 10006-5 10006 10007 10008 Basic UDI: D967ETTF1468	□ 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: Etching 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#
D)0/E1111400			
Device :70 Etching Materials (Actino Liquid)	☐ Class III ☐ Class IIb implantable (non-exempted)	⊠ N/A	☑ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123
Article No. 10009	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	Certificate or
Basic UDI : D967ETTF1468	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number: Etching 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 :71	□ Class III	⊠ N/A	☐ Certification as follows:
Etching Materials (Microgel SF)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 10010 10011 Basic UDI:	☐ Class IIb / Class IIb implantable (exempted) ☑ Class IIa ☐ Class I devices in sterile condition	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Etching Material	or □ Evidence that a competent authority of a Member State had



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function		granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device :72	☐ Class III	⊠ N/A	☑ Certification as follows:
Etching Materials (Cera Etch)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb implantable (exempted)		Certificate
10012 10013	⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
Basic UDI:	☐ Class I devices in sterile condition	Individual Article number: Etching Material	☐ Evidence that a competent au-
D967ETTF1468	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
Device :73	□ Class III	⊠ N/A	⊠ Certification as follows:
Auxiliary Dental Materials(Silane X)	☐ Class IIb implantable (non-exempted)		Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-	or	Certificate
10014 10015	plantable (exempted) ⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
Basic UDI:	☐ Class I devices in sterile condition	Individual Article number: Auxiliary Dental Materials	☐ Evidence that a competent au-
D967AMTF0322	☐ Class I devices with measuring function	,	thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable cus-		Evidence #1; CA#
	tom-made-device		Evidence #2; CA#
D : 51			
Device :74 Auxiliary Dental Materi-	☐ Class III☐ Class IIb implantable☐	⊠ N/A	☐ Certification as follows: Certificate # G10953770008,
als(Micron Dentin Conditioner)	(non-exempted)	or	Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb implantable (exempted)		Certificate
30010-1	⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
Basic UDI:	☐ Class I devices in sterile condition	Individual Article number: Auxiliary Dental Materials	☐ Evidence that a competent au-
D967AMTF0322	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or
	☐ Class III implantable custom-made-device		Art.97 (1) Evidence #1; CA#
	toni-made-device		Evidence #2; CA#
	_		
Device :75	☐ Class III	⊠ N/A	☐ Certification as follows:
Auxiliary Dental Materials(Ultra Dry)	☐ Class IIb implantable (non-exempted)		Certificate # G10953770008, Rev.00; NB# 0123



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer 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.	☐ Class IIb / Class IIb implantable (exempted)	or	Certificate
40033 40034	☐ Class IIa☐ Class I devices in sterile	☐ Identification of the corresponding device under MDD/AIMDD	or
Basic UDI : D967AMTF0322	condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number: Auxiliary Dental Materials	☐ 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.	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb im-	⊠ N/A or	☐ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123 Certificate
40035 Basic UDI D967AMTF0322	plantable (exempted) ⊠ Class IIa □ Class I devices in sterile	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	or
	condition ☐ Class I devices with measuring function ☐ Class III implantable cus-	Auxiliary Dental Materials	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	tom-made-device		Evidence #1; CA# Evidence #2; CA#
Device :77	□ Class III	⊠ N/A	☐ Certification as follows:
Auxiliary Dental Materials(Platina Hi Gloss)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No. 50001	☐ Class IIb / Class IIb implantable (exempted)	☐ Identification of the correspond-	Certificate
Basic UDI :	⊠ Class IIa	ing device under MDD/AIMDD	or
D967AMTF0322	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number: Auxiliary Dental Materials	☐ 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#
D : 70		57.37.4	5 10 (0.00)
Device :78 Auxiliary Dental Materials(ACE)	☐ Class III ☐ Class IIb implantable (non-exempted)	⊠ N/A	☐ Certification as follows: Certificate # G10953770008, Rev.00; NB# 0123
Article No. 50002	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	or ☐ Identification of the corresponding device under MDD/AIMDD	Certificate
Basic UDI : D967AMTF0322	☐ Class I devices in sterile condition ☐ Class I devices with meas-	Individual Article number: Auxiliary Dental Materials	☐ Evidence that a competent authority of a Member State had
	uring function ☐ Class III implantable custom-made-device		granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Device :79	☐ Class III	⊠ N/A	☐ Certification as follows:
Auxiliary Dental Materials(Spectra -Fresh Mint,	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Orange, Pineapple, Straw- berry, and fresh Fruit	☐ Class IIb / Class IIb im-	OI	Certificate
Prophylaxis Paste)	plantable (exempted)	☐ Identification of the correspond-	
Article No.	⊠ Class IIa	ing device under MDD/AIMDD	or
50005	☐ Class I devices in sterile condition	Individual Article number:	
50005-1	☐ Class I devices with meas-	Auxiliary Dental Materials	☐ Evidence that a competent authority of a Member State had
50006 50007	uring function		granted acc. MDR, Art.59 (1) or
50008	☐ Class III implantable cus-		Art.97 (1) Evidence #1; CA#
50009 50010	tom-made-device		Evidence #1, CA# Evidence #2; CA#
Basic UDI :			
D967AMTF0322			
Device :80	☐ Class III	⊠ N/A	☑ Certification as follows:
Auxiliary Dental Materials(Reveal)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb im-		Certificate
80002	plantable (exempted) ⊠ Class IIa	☐ Identification of the correspond-	or
Basic UDI :	☐ Class I devices in sterile	ing device under MDD/AIMDD Individual Article number:	OI
D967AMTF0322	condition	Auxiliary Dental Materials	☐ Evidence that a competent au-
	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
	tom made device		Evidence #2; CA#
Device :81	☐ Class III	⊠ N/A	☐ Certification as follows:
Auxiliary Dental Materials(Gingiva Shield VLC)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.	☐ Class IIb / Class IIb implantable (exempted)		Certificate
90010 90011	⊠ Class IIa	☐ Identification of the corresponding device under MDD/AIMDD	or
70011	☐ Class I devices in sterile	Individual Article number:	
Basic UDI:	condition	Auxiliary Dental Materials	☐ Evidence that a competent au-
D967AMTF0322	☐ Class I devices with measuring function		thority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)
	☐ Class III implantable custom-made-device		Evidence #1; CA#
	ISIII IIMAG GOVIOC		Evidence #2; CA#
Device :82	☐ Class III	⊠ N/A	☐ Certification as follows:
Auxiliary Dental Materials(Silano-X)	☐ Class IIb implantable (non-exempted)	or	Certificate # G10953770008, Rev.00; NB# 0123
Article No.			Certificate



Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device :83 Auxiliary Dental Materials (Crysta Dentin Conditioner) Article No. 30021 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 ☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ 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 ☑ N/A or ☐ 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# □ 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		☐ 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		☐ 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 applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device :86 Zinc Oxide Eugenol Tem-	☐ Class III	⊠ N/A	☑ Certification as follows:
porary Filling Material (Zinconol)	☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb im-	or Rev.00; NB# 00 Certificate ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: Zinc Oxide Eugenol Temporary Filling Material ☐ Evidence that thority of a Men	Certificate # G10953770008, Rev.00; NB# 0123 Certificate
Article No. 30015 30015-1 30016 Basic UDI: D967ZETF069M	plantable (exempted) ⊠ Class IIa □ Class I devices in sterile condition □ Class I devices with measuring function □ Class III implantable cus-		☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or
	tom-made-device		Evidence #1; CA# Evidence #2; CA#



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI- DI (under MDR applica- tion)	MDR Device classification (as proposed by the manu- facturer and verified during application review)	If the MDR device is a substitute device, identification of the corre- sponding 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 inter- nal reference traceable to each version of the letter	Action
2024-05-26	TPS3224_AR	Initial issue