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

TÜV SÜD 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 078535 0039 Rev. 00

Manufacturer:

3M Deutschland GmbH
Carl-Schurz-Straße 1
41453 Neuss
GERMANY

Facility(ies):

3M Deutschland GmbH
ESPE Platz, 82229 Seefeld, GERMANY

3M Deutschland GmbH
Ohmstraße 3, 86899 Landsberg, GERMANY

Product Category(ies):

Implant materials for dentistry as filling materials as well as crown and bridge materials, luting cements, adhesives, etching agents and micro-blasters, dental materials for surface preparation and endodontic posts with corresponding drills

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.: 713158370

Valid from: 2019-09-25
Valid until: 2024-05-26

Date, 2019-09-25

Stefan Preiß
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

3M Deutschland GmbH

Carl-Schurz-Straße 1
41453 Neuss

☎+49 (0)2131/140
🖷+49 (0)2131/142649
Internet: www.3M.de
E-Mail: innovation.de@3M.com
WEEE-Reg.-Nr. DE 36963167
VAT-ID: DE 120679179

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	3M Deutschland GmbH
Manufacturer address and contact details	Carl-Schurz-Str. 1 41453 Neuss Germany
Single Registration Number (SRN) (if available)	DE-MF-000012859

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

Notified body name (if applicable)	TÜV SÜD Product Service GmbH □ See attached schedule
Notified body number (if applicable)	0123 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 078535 0039 □ See attached schedule

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

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	May 26, 2024 □ See attached schedule
End date of extended validity/transition period	December 31, 2028 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

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

namely by fulfilling the following conditions:

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

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

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

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

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

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

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

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

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

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

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

➢ **Upclassified devices**

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

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☒ A QMS in accordance with Article 10(9) MDR is in place.
- ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

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

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

Signed for and on behalf of the manufacturer:

i.V. Desi W. Soegiarto

Dr. Desi W. Soegiarto
Manager Regulatory Medical Devices

Seefeld/February 12, 2024
Location/Date

Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Clinpro Glycine Prophy Powder	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Durelon	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Durelon Maxicap	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Etchant Dispensing Tips	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Lava Plus	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Micro Mixing Tips	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Micro Mixing Tips incl. Elongation Tips	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA

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

Mixing Tips regular	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Mixing Tips wide incl. Endo Tips	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Mixing Tips wide incl. Intraoral Tips	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
RelyX Temp NE	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
RelyX Ultimate	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
RelyX Ultimate Clicker	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
RelyX Universal	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Scotchbond Universal Etchant	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Scotchbond Universal	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Scotchbond Universal Plus	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Single Bond Universal	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Single use brushes	G1 078535 0039	May 26, 2024	TÜV SÜD Product Service GmbH (0123)	TÜV SÜD Product Service GmbH (0123)	December 31, 2028	NA
Express 2 Putty Quick	NA	NA	NA	NA	December 31, 2028	NA
Express 2 Putty Soft	NA	NA	NA	NA	December 31, 2028	NA

Express XT Putty Quick	NA	NA	NA	NA	December 31, 2028	NA
Express XT Putty Soft	NA	NA	NA	NA	December 31, 2028	NA
Dimension Garant L	NA	NA	NA	NA	December 31, 2028	NA
Dimension Garant L Quick	NA	NA	NA	NA	December 31, 2028	NA
Dimension Penta H	NA	NA	NA	NA	December 31, 2028	NA
Dimension Penta H Quick	NA	NA	NA	NA	December 31, 2028	NA

Add value.
Inspire trust.

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

3M Deutschland GmbH
Carl-Schurz-Straße 1
41453 Neuss

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
078535	713172096	+49 40 840521-117 Falko.Doberenz@tuvsud.com		2024-03-26	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 078535 0046 Rev. 00

Reference: 713172096

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000012859

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 Directive..

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC

(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; 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 078535 0046 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-03-26

TÜV SÜD Product Service GmbH
Medical and Health Services

Lazarus D.
Lazarus D. (Mar 26, 2024 14:47 GMT+1)

David Lazarus
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir
Michael Mauermeir (Mar 26, 2024 14:43 GMT+1)

Michael Mauermeir
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
0608223276102000000027DW Elongation Tip Micro Mixing Tips Micro Mixing Tips with Elongation Tips	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000030DK Clinpro Glycine Prophy Powder	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000036DX **0608223276102000000037DZ** Durelon	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000035DV Durelon Maxicap	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000034DT Etchant Dispensing Tip	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000043DU **0608223276102000000042DS** Lava Plus Lava Esthetic	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000033DR Mixing Tips Regular Mixing Tips Wide	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000021DJ RelyX Temp NE	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000024DQ RelyX Ultimate RelyX Ultimate Clicker	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000022DL RelyX Universal	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000025DS Scotchbond Universal Scotchbond Universal Plus Single Bond Universal	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000029E2 Scotchbond Universal Etchant	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123
0608223276102000000032DP single use brush (disposable brush) Brushes M	☒ Class IIa	☒ N/A	☒ Certification as follows: G1 078535 0039 Rev. 00 NB0123

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
0608223276102000000055E3 Express 2 Putty Quick Express 2 Putty Soft Express XT Putty Quick Express XT Putty Soft	☒ Class IIa	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
0608223276102000000057E7 Dimension Garant L Dimension Garant L Quick	☒ Class IIa	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
0608223276102000000056E5 Dimension Penta H Dimension Penta H Quick	☒ Class IIa	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-03-26	713172096	Initial issue