TÜVNORD

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

Ultradent Products, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, UT 84095
USA

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Am TÜV 1
45307 Essen
Germany

Phone: +49 201 825 2236

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TÜV®

Reference	Contact	Direct Dial	Date
No.: 8003062306	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	31 August 2023

Notified Body Confirmation Letter
Reference: 8003062306

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, TÜV NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 on NANDO, has 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 following manufacturer:

Ultradent Products, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, UT 84095
United States of America
SRN Number: US-MF-000013697

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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, by the 20 Mar 2023 for the relevant devices.

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of the Notified Body,

TÜVNORD i. V.
Digital unterschrieben von Mühlenberg Kevin
Datum: 2023.09.01 08:07:42 +02'00'

i. V. Kevin Mühlenberg
Head of Project Management

Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD i. A.
Digital unterschrieben von Mestmacher Bodo
Datum: 2023.12.15 15:56:38 +01'00'

i. A. Bodo Mestmacher
TIC Manager MDR

Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
Astringident	IIa	N/A	44 232 090234, NB 0044
Astringident X	IIa	N/A	44 232 090234, NB 0044
Citric Acid 20%	IIa	N/A	44 232 090234, NB 0044
ClearTemp LC	IIa	N/A	44 232 090234, NB 0044
Composite Wetting Resin	IIa	N/A	44 232 090234, NB 0044
EDTA 18% Solution	IIa	N/A	44 232 090234, NB 0044
Enamelast	IIa	N/A	44 232 090234, NB 0044
EndoREZ Accelerator	IIa	N/A	44 232 090234, NB 0044
EndoREZ Dual Care	IIa	N/A	44 232 090234, NB 0044
EndoREZ Points	IIa	N/A	44 232 090234, NB 0044
File-Eze EDTA	IIa	N/A	44 232 090234, NB 0044
Mosaic Universal Composite	IIa	N/A	44 232 090234, NB 0044
Opal Band Cement	IIa	N/A	44 232 090234, NB 0044
Opal Bond Flow	IIa	N/A	44 232 090234, NB 0044
Opal Bond MV	IIa	N/A	44 232 090234, NB 0044
Opal Etch	IIa	N/A	44 232 090234, NB 0044
Opal Seal	IIa	N/A	44 232 090234, NB 0044
Opalescence Boost PF 40%	IIa	N/A	44 232 090234, NB 0044
Opalescence Endo	IIa	N/A	44 232 090234, NB 0044
Opalescence Quick PF 45%	IIa	N/A	44 232 090234, NB 0044
Peak SE Primer	IIa	N/A	44 232 090234, NB 0044
Peak Universal Bond	IIa	N/A	44 232 090234, NB 0044
PermaFlo	IIa	N/A	44 232 090234, NB 0044
PermaFlo DC	IIa	N/A	44 232 090234, NB 0044
PermaFlo Pink	IIa	N/A	44 232 090234, NB 0044
PermaFlo Purple	IIa	N/A	44 232 090234, NB 0044
PermaSeal	IIa	N/A	44 232 090234, NB 0044
Porcelain Etch	IIa	N/A	44 232 090234, NB 0044
PQ1	IIa	N/A	44 232 090234, NB 0044
Sable Seek Caries Indicator	IIa	N/A	44 232 090234, NB 0044
Seek Caries Indicator	IIa	N/A	44 232 090234, NB 0044
Silane	IIa	N/A	44 232 090234, NB 0044
Transcend	IIa	N/A	44 232 090234, NB 0044
Ultra-Bend Plus	IIa	N/A	44 232 090234, NB 0044
UltraCal XS	IIa	N/A	44 232 090234, NB 0044
Ultra-Etch 35%	IIa	N/A	44 232 090234, NB 0044
UltraEZ	IIa	N/A	44 232 090234, NB 0044
UltraSeal XT hydro	IIa	N/A	44 232 090234, NB 0044
UltraSeal XT Plus	IIa	N/A	44 232 090234, NB 0044
Unicore Post	IIa	N/A	44 232 090234, NB 0044
Universal Dentin Sealant	IIa	N/A	44 232 090234, NB 0044
ViscoStat	IIa	N/A	44 232 090234, NB 0044
ViscoStat Clear	IIa	N/A	44 232 090234, NB 0044

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
FORMA Composite	IIa	N/A	N/A
UltraSeal XT hydro with Bioprotection by Nobio	IIa	N/A	N/A
UltraSeal XT Plus with Bioprotection by Nobio	IIa	N/A	N/A
Unicore Drill	IIa	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023.08.31	21-3982 CSA	Initial issue

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	Ultradent Products, Inc
Manufacturer address and contact details	505 West Ultradent Drive (102000 South) South Jordan, Utah 84095 USA
Single Registration Number (SRN) (if available)	US-MF-000013697

Authorised Representative name (if applicable)	Ultradent Products, GMBH
Authorised Representative address and contact details	AM Westhover Berg 30, Cologne, 51149 Germany
Single Registration Number (SRN) (if available)	DE-AR-000006666

Notified body name (if applicable)	X See attached schedule
Notified body number (if applicable)	X See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	X See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	X 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.

End date of extended validity/transition period	X 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)

  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.

[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

☒ 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:

Karen Kakunes

Karen Kakunes RN, BSN - PRRC
Senior Vice President – Quality Assurance and Regulatory Affairs
Ultradent Products, Inc.
Karen.kakunes@ultradent.com

Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Astringident	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Astringident X	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Citric Acid 20%	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
ClearTemp LC	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Composite Wetting Resin	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
EDTA 18% Solution	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Enamelast	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A

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

EndoREZ Accelerator	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
EndoREZ Dual Care	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
EndoREZ Points	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
File-Eze EDTA	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Mosaic Universal Composite	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Opal Band Cement	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Opal Bond Flow	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Opal Bond MV	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Opal Etch	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Opal Seal	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Opalescence Boost PF 40%	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Opalescence Endo	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Opalescence Quick PF 45%	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A

Peak SE Primer	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Peak Universal Bond	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
PermaFlo	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
PermaFlo DC	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
PermaFlo Pink	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
PermaFlo Purple	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
PermaSeal	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Porcelain Etch	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
PQ1	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Sable Seek Caries Indicator	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Seek Caries Indicator	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Silane	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Transcend	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A

Ultra-Bend Plus	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
UltraCal XS	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Ultra-Etch 35%	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
UltraEZ	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
UltraSeal XT hydro	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
UltraSeal XT Plus	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Unicore Post	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
Universal Dentin Sealant	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
ViscoStat	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A
ViscoStat Clear	Certificate #44 232 090234	26.05.2024	TUV Nord Cert GmbH, NB# 0044	TUV Nord Cert GmbH, NB# 0044	31.12.2028	N/A