EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

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

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Dentalprodukte
Dental products

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 44 232 090234
Bericht Nr. / *Report No.* 3525 2375

Gültigkeit / *Validity*
von / *from* 2020-08-18
bis / *until* 2024-05-26
Edition 4

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-08-18

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 44 232 090234

Produkte der Klasse IIa *Products of class IIa*	UMDNS
Gleitmittel (dental) / *Lubricating Jellies (Dental)*	12-401
Hohlraumeinsatz / *Cavity Liners*	16-182
Hohlraumlack / *Cavity Varnish*	16-183
Wurzelkanalstift / *Root Canal Posts*	16-202
Zement, dental, Harzkomposit / *Cement, Dental, Resin Composite*	16-707
Zubehörkit, Wiederherstellungsmaterial, dental, Krone und Brücke / *Restorative Material Kits, Dental, Crown and Bridge*	16-733
Verbundwiederherstellungskit, dental / *Composite Restorative Material Kits, Dental*	16-734
Verbundwiederherstellungskit, dental, lichtaushärtend / *Composite Restorative Material Kits, Light-Cured*	16-736

Bericht Nr. / *Report No.* 3525 2375

Gültigkeit / *Validity*
von / *from* 2020-08-18
Edition 5

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-08-18

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 44 232 090234

Produkte der Klasse IIa *Products of class IIa*	UMDNS
Verbundwiederherstellungskit, dental, sonstige / *Composite Restorative Material Kits, Dental, Other*	16-740
Endodontik-Füllmaterial / *Endodontic Filling Materials*	17-611
Wiederherstellungsmaterial, dental, sonstige / *Restorative Materials, Dental, Other*	17-619
Dental-Ätzflüssigkeit / *Dental Etching Liquids*	17-737
Zement, orthodontisch / *Cement, Orthodontic*	17-943
Hämostatikmittel / *Hemostatic Media*	17-944
Zement, dental / *Cement, Dental*	11-150
Scheibe, abrasiv / *Disks, Abrasive*	16-470
Bohrer, dental, Karbid / *Burs, Dental, Carbide*	16-668
Bohrer, dental, Diamant / *Burs, Dental, Diamond*	16-670

Bericht Nr. / *Report No.* 3525 2375

Gültigkeit / *Validity*
von / *from* 2020-08-18
Edition 5

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2020-08-18

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

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

TÜV NORD CERT GmbH
Am TÜV 1
45307 Essen
Germany

Phone: +49 201 825 2236

medical@tuev-nord.de
tuev-nord-cert.com/en

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