ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 029125 0023 Rev. 01

Manufacturer: **Coltène/Whaledent AG**
Feldwiesenstrasse 20
9450 Altstätten
SWITZERLAND

Product Category(ies): **Materials for Restorative Dentistry**
Burs / Polishers used in Dentistry

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 029125 0023 Rev. 01

Report No.: 713149029

Valid from: 2021-05-25
Valid until: 2024-05-26

Date, 2021-05-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Coltène/Whaledent AG
Feldwiesenstrasse 20
9450 Altstätten
SWITZERLAND

Your reference/letter of	Our reference/name	E-mail	Tel. extension	Date	Page
029125	0713331764_CL	Tim.Gebauer@tuvsud.com	+49 89 50084 985	2024-04-24	1 of 10

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 029125 0027 Rev. 00

Reference: 0713331764_CL

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: CH-MF-000015779

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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further 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 029125 0027 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-24

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 909449
24.04.2024
Tim Gebauer
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Konrad Fackler
Konrad Fackler (24. April 2024 13:53 GMT+2)

Konrad Fackler
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **BRILLIANT COMPONEER**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 2 **BRILLIANT CRIOS** **BRILLIANT CRIOS DISC**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 3 **BRILLIANT EVERGLOW** **BRILLIANT EVERGLOW FLOW**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 4 **BRILLIANT FLOW**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 5 **BRILLIANT NG**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 6 **COLTOSOL F**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 7 **COOL TEMP NATURAL**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) 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 8 **DUOTEMP**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 9 **ETCHANT GEL S**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 10 **FILL-UP!**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 11 **MIRIS2**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 12 **ONE COAT 7 UNIVERSAL** **ONE COAT 7.0** **ONE COAT BOND** **ONE COAT BOND SL** **ONE COAT SELF-ETCHING BOND**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 13 **A.R.T BOND**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) 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 **PARABOND ADHESIVE**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) 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 15 **PARACORE**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 16 **SOLOCEM**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 17 **SYNERGY D6** **SYNERGY D6 FLOW**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 18 **SYNERGY (NANO FORMULA)**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 19 **TEMPOSIL 2**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 20 **DIATECH CARBIDE BURS** **DIATECH DIAMOND INSTRUMENTS** **DIATECH SILICONE POLISHERS** **DIATECH Z-REX**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 21 **KENDA DENTAL POLISHER**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 22 **JIFFY POLISHING**	☐ 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:	☒ Certification as follows: Certificate #: G1 029125 0023 Rev. 01 NB #0123 (TÜV Süd) or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

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

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-24	0713331764_CL	Initial issue

COLTENE

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	Coltène/Whaledent AG
Manufacturer address and contact details	Feldwiesenstrasse 20 9450 Altstätten Switzerland
Single Registration Number (SRN)	CH-MF-000015779

Authorised Representative name	Coltène/Whaledent GmbH + Co. KG
Authorised Representative address and contact details	Raiffeisenstraße 30 89129 Langenau GERMANY
Single Registration Number (SRN)	DE-AR-000005719

Notified body name	TÜV Süd Product Service GmbH
Notified body number	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 029125 0023 Rev.01
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26
End date of extended validity/transition period	2028-12-31

[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.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** 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 Certificates** as listed above or in the attached schedule

- Directive Certificate covering the listed devices were issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards and after 20 March 2023.

  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.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place.

➢ **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:

Coltène/Whaledent AG
Altstätten, 02.05.2024

Coltène/Whaledent AG
Feldwiesenstrasse 20
9450 Altstätten/Switzerland

Patrick Vortanz
Manager Quality Management
Person Responsible for Regulatory Compliance

Schedule of Devices

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

Identification of the device(s)[2] (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)
BRILLIANT COMPONEER	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
BRILLIANT CRIOS	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
BRILLIANT CRIOS DISC	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
BRILLIANT EVERGLOW	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
BRILLIANT EVERGLOW Flow	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH;	TÜV Süd Product Service GmbH;	2028-12-31	n.a.

[2] 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)

			NB 0123	NB 0123		
BRILLIANT FLOW	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
BRILLIANT NG	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
COLTOSOL F	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
COOL TEMP NATURAL	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
DUOTEMP	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
ETCHANT GEL S	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
FILL-UP!	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
MIRIS2	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.

ONE COAT 7 UNIVERSAL	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
ONE COAT 7.0	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
ONE COAT BOND	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
ONE COAT BOND SL	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
ONE COAT SELF-ETCHING BOND	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
A.R.T BOND	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
PARABOND ADHESIVE	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
PARACORE	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.

SOLOCEM	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
SYNERGY D6	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
SYNERGY D6 FLOW	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
SYNERGY (NANO FORMULA)	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
TEMPOSIL 2	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
DIATECH CARBIDE BURS	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
DIATECH DIAMOND INSTRUMENTS	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
DIATECH SILICONE POLISHERS	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.

DIATECH Z-REX	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
KENDA DENTAL POLISHER	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.
JIFFY POLISHING	G1 029125 0023 Rev.01	2024-05-26	TÜV Süd Product Service GmbH; NB 0123	TÜV Süd Product Service GmbH; NB 0123	2028-12-31	n.a.