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Certificate covering the listed devices were issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards and after 20 March 2023.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