

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

Coltène/Whaledent GmbH + Co. KG
Raiffeisenstraße 30
89129 Langenau
Germany

for the scope

**root canal filling materials, paper points, aspirator tips,
medicated gelatin sponges, root canal files,
dental rotary handpiece with engine**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex II – excluding Section 4
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-08-06
Valid until	2024-05-26
Registration no.	D1007900062
Report no.	P20-01093-182998
Stuttgart	2020-08-06



Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

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
- 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 GmbH + Co. KG
Manufacturer address and contact details	Raiffeisenstraße 30 89129 Langenau Germany
Single Registration Number (SRN)	DE-MF-000005717

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

Notified body name	mdc medical device certification GmbH
Notified body number	0483
Directive Certificate numbers to which this confirmation is made	D1007900062 D1007900060
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

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificates** 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

Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021, have not been withdrawn afterwards and expired 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 devices 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.

➤ **Devices as listed in the attached schedule**

- The devices continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The devices 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 GmbH + Co. KG
Langenau, 29.04.2024

Barbara Wellbrock
Director QM/QC/RA
03.05.2024
 Einfache elektronische Signatur
Signiert auf Skribble.com

Barbara Wellbrock
Director QM/QC/RA
Person Responsible for Regulatory Compliance

Martin Schlüter
Vize Präsident R&D und Innovationen COLTENE Group / General Manager Coltène/Whaledent GmbH & Co. KG
30/04/2024
 Simple electronic signature
Signed on Skribble.com

Dr. Martin Schlüter
General Manager

Schedule of Devices

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

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Root canal filling materials: - Guttapercha Points - GuttaFlow 2 - GuttaFlow bioseal	D1007900062	26.05.2024	mdc medical device certification GmbH; NB 0483	mdc medical device certification GmbH; NB 0483	31.12.2028	n.a.
Paper Points	D1007900062	26.05.2024	mdc medical device certification GmbH; NB 0483	mdc medical device certification GmbH; NB 0483	31.12.2028	n.a.
Root canal files: HyFlex rotary files	D1007900062	26.05.2024	mdc medical device certification GmbH; NB 0483	mdc medical device certification GmbH; NB 0483	31.12.2028	n.a.
Sterile sleeves for tubes: Steri-sleeve	D1007900060	26.05.2024	mdc medical device certification GmbH; NB 0483	mdc medical device certification GmbH; NB 0483	31.12.2028	n.a.

Coltène/Whaledent GmbH + Co. KG
Raiffeisenstraße 30
89129 Langenau
Germany

Notified Body Confirmation Letter

Registration no.: D1007900070

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 mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0483 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:

**Coltène/Whaledent GmbH + Co. KG
Raiffeisenstraße 30
89129 Langenau
Germany
SRN: DE-MF-000005717**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a 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 a 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 20 March 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 Regulation (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)

Stuttgart, 2024-03-27



Head of Notified Body

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
Root canal filling materials: - Guttapercha Points - GuttaFlow 2 GuttaFlow bioseal	Class IIa	N/A	Certificate D1007900062; NB 0483
Paper Points	Class IIa	N/A	Certificate D1007900062; NB 0483
Root canal files: HyFlex rotary files	Class IIa	N/A	Certificate D1007900062; NB 0483
Sterile sleeves for tubes: Steri-sleeve	Class I devices placed on the market in sterile condition	N/A	Certificate D1007900060; NB 0483

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-03-27	D1007900070	Initial