

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



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**

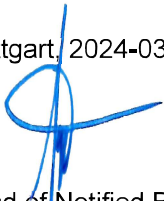
The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which a MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the 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