

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

**sterile covers,
sterile sleeves for tubes**

has introduced and applies a

Quality System

for the aspects of manufacture concerned with securing and
maintaining sterile conditions as specified in Annex V, Section 3.

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

Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2020-02-19
Valid until	2024-05-26
Registration no.	D1007900060
Report no.	P19-00500-144160
Stuttgart	2020-02-19

Head of Certification Body



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bei Arzneimitteln und
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