

Certificate

We hereby certify the company

DETAX GmbH
Carl-Zeiss-Straße 4
76275 Ettlingen
Germany

the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

development, manufacturing and distribution of dental products, otologic products and
orthopedic impression materials

An audit by mdc has proven that this quality management system meets the requirements of the following
standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2026-06-25
Valid until 2029-06-24

Registration No. D1002700061
Report No. P26-00284-357503

Stuttgart, 2026-06-25


Certification Body