EC CERTIFICATION

TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapter II

We hereby declare that a conformity assessment of the technical documentation according to Annex II and III has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the technical documentation for the below listed products conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

ITL Dental

31 Peters Canyon, Irvine, California, 92606, United States

Manufacturer SRN: US-MF-000029053

Authorised Representative Name

EUCEREP

Roald Dahllan 33, 5629MC- Eindhoven; The Netherlands

Scope:

Dental Implant System, Class IIa, Class IIb and Class IIb implant.

*For the class IIb devices covered by this certificate an EU Quality Management System certificate according to Annex IX is also required.

Certificate Number:
28620175433

Revision:
00

Initial Certification Date:
15 May 2024

Certificate Decision Date:
15 May 2024

Certificate Issue Date:
15 May 2024

Certificate Expiry Date:
19 March 2029

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
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Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.