

EU Quality Management System Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX
Chapter I and III (Class IIa, IIb and III Devices)



Certificate Number: M.2025.MDR.1082

Manufacturer Name : Erfadent Diş Malzemeleri İthalat İhracat Sanayi Ve Ticaret Limited Şirketi

Manufacturer Address : Orhaniye Mah. 614 Cad. No: 19a Kahramankazan / Ankara, Türkiye

Single registration number-SRN : TR-MF-000018267

Authorised Representative Name (If applicable) : N/A

Authorised Representative Address : N/A

Product Scope : See the product list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality management system in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter I and Chapter III, UDEM Adriatic d.o.o. hereby declares that the requirements of Annex IX (Chapter I and Chapter III) of the Regulation (EU) 2017/745 have been met for the listed products in this certificate.

The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according to Annex IX Chapter I Section 3 of the aforementioned Regulation.

The report referenced below summarizes the results of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.

For Class III and Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of Regulation (EU) 2017/745, covered by this certificate, an EU Technical Documentation Assessment Certificate is required before placing them on the market.

Report Number : MDR.1480
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UDEM Adriatic d.o.o.
General Manager



If any, Previous Certificate(s) No: -

UDEM Adriatic d.o.o. is a Notified Body (Identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

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