EU Technical Documentation Assessment Certificate

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

Certificate Number: M.2025.MDR.1081-1

Manufacturer Name	: Erfadent Diş Malzemeleri İthalat İhracat Sanayi Ve Ticaret Limited Şirketi
Manufacturer Address	: Orhaniye Mah. 614 Cad. No: 19a Kahramankazan / Ankara, Turkiye
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 assessment of technical documentation for the abovementioned manufacturer in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter II, UDEM Adriatic d.o.o. hereby declares that the technical documentation of the listed products in this certificate meets the applicable requirements of the Regulation (EU) 2017/745.
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 Quality Management System Certificate in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter I and Chapter III is also required before placing them on the market.
The validity of this certificate is dependent on the validity of the accompanying EU Quality Management System Certificate.

Report Number	: MDR.1480
Date of First Issue	: 04.08.2025
Recertification Date	: -
Revision Date/No	: 12.12.2025/02
Date of Expiry	: 03.08.2029

If any, Previous Certificate(s) No: -

UDEM Adriatic d.o.o.
General Manager

UDEM Adriatic d.o.o. UDEM 2696

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

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