

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.2024.MDR.1052

Manufacturer Name : QUALL TEKNOLOJI ANONIM ŞİRKETİ
Manufacturer Address : Aydınlı Mahallesi Kimyacılar Organize Sanayi Bölgesi,
Organik Caddesi No:5 Tuzla/İstanbul/Türkiye
Single registration number-SRN : TR-MF-000037365
Authorised Representative Name (If applicable) : NA
Authorised Representative Address : NA
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 result 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.1560
Date of Issue : 28/10/2024
Recertification Date : -
Reissue Date/No : -
Date of Expiry : 27/10/2029

UDEM Adriatic d.o.o.
General Manager
Stamp - Signature

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.

Address: Radnička cesta 54/ R3 Zagreb- Croatia
E-Mail: info@udemadriatic.com **Web:** www.udemadriatic.com

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PRODUCT LIST COVERED BY THE CERTIFICATE

PRODUCT NAME	BASIC UDI-DI	RISK CLASS	EMDN CODE	MODEL	TYPE	INTENDED PURPOSE
QuallThermo Non-Contact Thermometer	86830712QTF2010QL	Class IIa	V0301010202	QTF2010	-	QuallThermo is a non-contact clinical thermometer used to measure the body temperature of people of all ages.

Conditions for or limitations to the validity of this certificate : none

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CERTIFICATE HISTORY		
Rev. No.	Rev. Date	Description of Revision
00	28/10/2024	Initial Certification



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