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.1073

Manufacturer Name	: Nefes Medikal Teknoloji Sanayi Ticaret Limited Şirketi
Manufacturer Address	: Cihangir Mah. Kemal Türkler Sok. No:5/1A Avcılar/ İstanbul, Türkiye
Single registration number-SRN	: TR-MF-000038588
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 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.1739
Date of First Issue	: 05.05.2025
Recertification Date	: -
Revision Date/No	: -
Date of Expiry	: 04.05.2029

UDEM Adriatic d.o.o.
General Manager

If any, Previous Certificate(s) No: -

* EMA/EX/0000232089 numbered scientific opinion of Expert Panel on 10/01/2025 in the scope of (EU) 2017/745 Medical Devices Regulation Article 54 and Annex IX, Section 5.1 has been considered.

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
VENTISENSE Mechanical Ventilator	868419012ventisenseFU	Class IIb	Z1203010504	VENTISENSE PRO VENTISENSE 60 VENTISENSE 40	VENTISENSE is used to artificially maintain respiratory function when the lungs are unable to perform the vital function of respiration for any reason. The device is for adult and pediatric patients weighing more than 5 kg with a tidal volume of 50 ml and above. It is designed for use in the home treatment processes of adult and pediatric patients. VENTISENSE PRO is for adult and pediatric patients. VENTISENSE 60 is for adult patients. VENTISENSE 40 is for pediatric patients.

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

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CERTIFICATE HISTORY		
Revision No	**Revision Date**	**Description of Revision**
00	05.05.2025	Initial Certification

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