# 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.1074**

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|---|---|
| **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.

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| **Report Number** | : MDR.1739 |
| **Date of First Issue** | : 05.05.2025 |
| **Recertification Date** | : - |
| **Revision Date/No** | : - |
| **Date of Expiry** | : 04.05.2030 |

**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.**

**Address:** Radnička cesta 54/ R3 Zagreb– Croatia
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## PRODUCT LIST COVERED BY THE CERTIFICATE

| PRODUCT NAME | BASIC UDI-DI | RISK CLASS | EMDN CODE | MODEL/ TYPE | INTENDED PURPOSE |
|---|---|---|---|---|---|
| AIRPAP Respiratory Therapy Device | 868419012SDCV4AIRPAP3S | Class IIa | Q03010299 | CPAP | AirPAP respiratory therapy device which is used in the treatment of respiratory disorders during sleep, regulates breathing and sleep quality by keeping the upper respiratory tract open during sleep. The positive pressure applied to the upper respiratory tract prevents apneas, hypopneas, snoring and flow restrictions by eliminating the negative pressure applied for inspiration, which is the most important collapsing power. AirPAP respiratory therapy device is suitable for use by adults and children weighing more than 30 kg/12 years and is designed for home or clinical applications. |
| | | | | AUTOCPAP | |
| | | | | BiLEVEL | |
| | | | | BiLEVEL-ST | |
| | | | | AUTOBiLEVEL | |
| | | | | BiLEVEL-VT | |
| | | | | ASV | |

**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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