

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.2023.MDR.1019

Manufacturer Name : Capnopharm GmbH
Manufacturer Address : Vor dem Kreuzberg 17, 72070 Tübingen, Germany
Single registration number-SRN : DE-MF-000033336
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 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.1667
Date of Issue : 16/05/2023
Recertification Date : -
Reissue Date/No : 13/06/2024/ 01
Date of Expiry : 15/05/2027

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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PRODUCT LIST COVERED BY THE CERTIFICATE

PRODUCT NAME	BASIC UDI-DI	RISK CLASS	EMDN CODE	MODEL	TYPE	INTENDED PURPOSE
CapnoPen© Sterile Endoscopic Nebulizer for Single Use	426239733CP-001KYK	Class IIb	G0308	CP-001L	-	The Capnopen® is an endoscopic nebulizer for medical delivery of therapeutic substances (chemotherapy, DNA, RNA, nano molecules, viruses, immunotherapy) as pressurized aerosols into body cavities.

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

CERTIFICATE HISTORY		
Rev. No.	Rev. Date	Description of Revision
00	16/05/2023	Initial Certification
01	13/06/2024	The model number has been changed from CP-001k to CP-001L



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