ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 063105 0052 Rev. 01

Manufacturer:

CA-MI S.r.l.
Via Ugo La Malfa, 13
Frazione Pilastro
43013 Langhirano (PR)
ITALY

SRN Manufacturer - IT-MF-000020076

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 063105 0052 Rev. 01

Report No.:	ITA1816546_CN ITA1816546_CN2
Preceding Certificate No.:	G10 063105 0052 Rev. 00
Valid from:	2024-10-31
Valid until:	2028-07-17
Date of Initial Issuance:	2024-01-03

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-10-31

Digitally signed by Granaci Boris
Date: 2026.05.21 13:12:27 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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No. G10 063105 0052 Rev. 01

Classification:	Class IIa
Device Group:	R060101 - COLD NEBULISATION SYSTEMS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	R0699 - NEBULISATION AND HUMIDIFICATION SYSTEMS - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z120105 - SURGICAL MEDICAL ASPIRATORS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z12080303 - BREAST PUMPS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z12159002 - AEROSOL EQUIPMENT
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z12080399 - VARIOUS CHILDBIRTH SUPPORT AND MATERNAL ASSISTANCE INSTRUMENTS - OTHER
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2024-01-03	ITA1816546	Initial issuance
01	2024-10-31	ITA1816546_CN ITA1816546_CN2	Supplemented: Device(s)/group of device(s) added

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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