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

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 011861 0631 Rev. 02

Manufacturer:

PARI GmbH, Spezialisten für effektive Inhalation
Moosstr. 3
82319 Starnberg
GERMANY

SRN Manufacturer - DE-MF-000006567

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 and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 011861 0631 Rev. 02

Report No.:	713234576
Preceding Certificate No.:	G10 011861 0631 Rev. 01
Valid from:	2024-02-06
Valid until:	2026-05-24
Date of Initial Issuance:	2021-05-25

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-02-06

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

Classification:	Class IIa
Device Group:	R9009 - RESPIRATORY THERAPY AIDS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	R060203 - INHALATION THERAPY HUMIDIFICATION LIQUIDS
Intended Purpose:	Inhalation solution is used to moisten the airways and as a secondary treatment for cold infections. It can also be used as a carrier solution for medications which, according to the manufacturer's instructions, may be diluted with isotonic saline solution for inhalation.

Classification:	Class IIa
Device Group:	R030103 - AEROSOL THERAPY MASKS AND SYSTEMS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	R060203 - INHALATION THERAPY HUMIDIFICATION LIQUIDS
Intended Purpose:	Inhalation solution is used to mobilise secretions in the respiratory tract in the event of mucous consolidation.

The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2021-05-25	713181777	-
01	2023-08-29	713223142	Supplemented: Device(s)/group of device(s) added
02	2024-02-06	713234576	Supplemented: Device(s)/group of device(s) added

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