



ID-Nr. 022-MDD-001/014

EC Declaration of Conformity for Medical Devices

In accordance with Annex II excluding (4) of Council Directive 93/42/EEC

We

PARI GmbH Spezialisten für effektive Inhalation

**Moosstraße 3
82319 Starnberg
GERMANY**

hereby declare under sole responsibility that the medical device

PARI LC Family (Type 022)

**(PARI LC, PARI LC PLUS/Turbo/Junior, PARI BABY, PARI LC STAR, PARI LC D,
PARI LC D SINUS)**

(Nebuliser for inhalation therapy)

GMDN Code: 35457

Risk Classification according to Council Directive 93/42/EEC, Annex IX: IIa

complies with the essential requirements of the

Council Directive 93/42/EEC (Medical Device Directive, MDD) dated 14th June 1993.

This Declaration remains valid at the latest until December 31, 2028 according to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices. The conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and the listed device and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service.

Compliance has been achieved in conformity with Annex I of the above named Directive.

The applied harmonized standards are listed in the technical documentation.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, D-80339 München, Germany

EC Quality System Certificate: Certificate No. G1 011861 0076 Rev. 02



Starnberg, April 19th 2024

Dr. Frank Bredl
- President -



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Attachment

This Declaration of Conformity is valid for the following configurations:

Number	Name
022B0004	LC Plus
022B0238	LC Plus Baby
022B0008	LC (Branding-JP)
022B0230	LC Star + EAV
022B0210	LC Disposable
022G3510	PARI COMPACT2 Year Pack (DE/AT)
022G3511	PARI COMPACT2 Year Pack (WE)
022G3513	PARI COMPACT2 Junior Year Pack (DE/AT)
022G3516	PARI COMPACT2 Year Pack (OE)
022G3518	PARI COMPACT2 Year Pack (RU)
022G4710	PARI BASIC Year Pack
022G5210	PARI COMPACT Year Pack
022G5240	PARI COMPACT Year Pack (Ost-EU)
022G8001	LC PLUS für Gerät
022G8010	PARI LC PLUS Year Package
022G8035	LC PLUS Klinikpack mit laufender Nummer
022G8100	PARI LC PLUS Vern. m. Schlauch
022G8101	PARI LC PLUS Vern. m. Schlauch (CTS)
022G8104	LC PLUS Vern. m. 1,2m-Schlauch
022G8107	LC PLUS Vernebler
022G8150	LC PLUS Vern. m.S. Australien
022G8700	PARI LC STAR Vernebler
022G8701	LC STAR (Japan)
022G8728	PARI LC D SINUS (CN)
022G8732	P*PARI LC Vernebler mit Mundstück (CN)
022G8736	PARI LCD Nebuliser with Mouthpiece (RoA)
022G8740	LC STAR Australien
022G8746	PARI LCD SINUS (RoA)
022G8781	PARI LC PLUS Verneblersset (CN)
022G9215	PARI LC PLUS Baby
022G8004	PARI LC PLUS (RU)
022G6000	PARI LC Vernebler (natur) ohne Schlauch