ID-Nr. 152-MDD-001-005

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 COMPACT2 (Type 152)

(Compressor for Inhalation Therapy)

GMDN Code: 31253

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.

CE 0123

Starnberg, May 02nd, 2024

Dr. Frank Bredl
- President -

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Attachment

This Declaration of Conformity is valid for the following configurations:

REF No.	Product Name	Annotations
152B1000	PARI COMPACT2	EU configuration (w/o UK)
152B1002	PARI COMPACT2	UK configuration
152B1006	PARI COMPACT2	CN configuration

END OF DOCUMENT