ID-Nr. 130-MDD-001-007

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 BOY (Type 130)

(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 May 26, 2024.

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 (Expiry: May 26, 2024)

CE 0123

Starnberg, May 12, 2021

Dr. Davia Viellechner
- President -

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Attachment

This Declaration of Conformity is valid for the following configurations:

REF No.	Product Name	Annotation
130B1000	PARI BOY Pro	EU configuration (w/o UK)
130B1003	PARI BOY Pro	JP configuration
130B1004	PARI BOY Pro	KR configuration
130B1006	PARI BOY Pro	CN configuration
130B1013	PARI GEN	France configuration
130B1020	PARI BOY Classic	EU configuration (w/o UK)
130B1022	PARI BOY Classic	UK configuration
130B1025	PARI BOY Classic	AUS/NZ configuration
130B1026	PARI BOY Classic	CN configuration
130B1031	PARI BOY Classic	IL configuration
130B1040	PARI BOY Junior	EU configuration, w/o UK
130B1043	PARI BOY Junior	JP configuration
130B1046	PARI BOY Junior	CN configuration

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