ID-Nr. 130-MDD-001-008

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 21, 2021

Dr. Davia Viellechner
- President -

ID-Nr. 130-MDD-001-008

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
130G0015	PARI BOY Classic Rental Set	Contains 130B1020 PARI BOY Classic compressor
130G1236	PARI BOY Classic Inhalation Device without nebuliser (CN)	Contains 130B1026 PARI BOY Classic compressor

END OF DOCUMENT