



ID-Nr. 085-MDD-002-009

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 SX (Type 085)*
(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.

***The product model PARI BOY SX covers the following variants: PARI BOY SX, PARI TurboBOY SX, PARI JuniorBOY SX, PARI BOY, PARI TurboBOY, PARI JuniorBOY, PARI BOY SX Waldhausen**

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)



Starnberg, May 12, 2021

Dr. Davia Viellechner
- President -



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Attachment

This Declaration of Conformity is valid for the following configurations:

REF Number	Product Name	Annotation(s)
085B1021	PARI BOY SX Waldhausen	230V/50Hz
085B3002	BOY SX	240V/50Hz
085B3009	BOY SX	220V/60Hz
085B3012	BOY SX	100V/50-60Hz
085B3015	BOY SX	220V/50Hz
085B3040	BOY SX	230V/50Hz
085B3055	BOY	200V/50 Hz, China Configuration
085B3200	TurboBOY SX	230V/50Hz
085B3218	TurboBOY SX	220V/50Hz
085B3255	TurboBOY	220V/50Hz, China Configuration
085B3300	JuniorBOY SX	230V/50Hz
085B3301	JuniorBOY SX	220V/50Hz
085B3312	JuniorBOY SX	100V/50-60Hz
085B3355	JuniorBOY	220V/50Hz, China Configuration

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