ID-Nr. 023-MDR-001-006

EU Declaration of Conformity for Medical Devices

In accordance with Annex IX

of **Medical Device Regulation (EU) 2017/745**

and in accordance with **RoHS Directive 2011/65/EU**
(Restriction of the use of certain hazardous substances in electrical and electronic appliances)

We

PARI GmbH, Spezialisten für effektive Inhalation
SRN (Single Registration Number): DE-MF-000006567
Moosstraße 3
82319 Starnberg
GERMANY

hereby declare under sole responsibility that the medical device

PARI LC SPRINT (Type 023)

(Nebuliser for inhalation therapy / Intended Purpose: The PARI LC SPRINT, PARI LC SPRINT Junior, PARI LC SPRINT STAR, PARI LC SPRINT BABY, PARI LC SPRINT COMPACT and PARI LC SPRINT CENTRAL nebulisers generate aerosol for inhalation for the therapy of the lower airways.)

Basic-UDI-DI (PARI LC SPRINT, PARI LC SPRINT Junior, PARI LC SPRINT STAR, PARI LC SPRINT BABY, PARI LC SPRINT COMPACT):
426002043-P023-1000-00G4

Basic-UDI-DI (PARI LC SPRINT CENTRAL):
426002043-P023-5800-00MG

PARI LC SPRINT Tracheo (Type 023)

(Nebuliser for inhalation therapy / Intended Purpose:
The "PARI LC SPRINT Tracheo with Adapter" and "PARI LC SPRINT Tracheo with Mask" nebulisers generate aerosols for inhalation for the therapy of the lower airways.)

Basic-UDI-DI: 426002043-P023-1080-00JU

PARI LC SPRINT SP (Type 023)

(Nebuliser for inhalation therapy / Intended Purpose:
PARI LC SPRINT SP (Type 023) nebulisers generate aerosol for inhalation for the therapy of the lower airways.)

Basic-UDI-DI: 426002043-P023-1501-00JC

Risk Classification according to Regulation (EU) 2017/745, Annex VIII: IIa

ID-Nr. 023-MDR-001-006

complies with the

Medical Device Regulation (EU) 2017/745

and complies with

RoHS Directive 2011/65/EU dated 8th June 2011

Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials:

- Lead (0.1 %)
- Mercury (0.1 %)
- Cadmium (0.01 %)
- Hexavalent chromium (0.1 %)
- Polybrominated biphenyls (PBB) (0.1 %)
- Polybrominated diphenyl ethers (PBDE) (0.1 %)

On 31st March 2015 the **Delegated Directive (EU) 2015/863** amended the list by following restricted substances:

- Bis(2-Ethylhexyl) phthalate (DEHP): 0.1%
- Benzyl butyl phthalate (BBP): 0.1%
- Dibutyl phthalate (DBP): 0.1%
- Diisobutyl phthalate (DIBP): 0.1%

This Declaration is effective for products placed on the market as of the date of issue and remains valid until a modification is necessitated by a conformity related change (resp. at the latest until the EU-Certificate listed below expires), whereupon a new conformity declaration will be issued.

The applied harmonised standards and common specifications are listed in the technical documentation.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65, D-80339 München, Germany,
EU certificate: No. G15 011861 0636 Rev. 01 (Expiry: 24.05.2031)

CE 0123

Starnberg, May 25th, 2026

Dr. Frank Bredl
- President -

ID-Nr. 023-MDR-001-006

Attachment

This Declaration of Conformity is valid for the following configurations:

Number	Name
023G1000	PARI LC SPRINT Vernebler
023G1001	LC SPRINT (Exp.)
023G1006	PARI LC SPRINT (Osteuropa)
023G1080	PARI LC SPRINT Tracheo with Adapter
023G1081	PARI LC SPRINT Tracheo with Adapter (WE)
023G1090	PARI LC SPRINT Tracheo with Mask
023G1091	PARI LC SPRINT Tracheo with Mask (WE)
023G1100	PARI LC SPRINT Junior Vernebler
023G1101	PARI LC SPRINT Junior Vernebler (Exp.)
023G1106	LC SPRINT Junior (Osteuropa)
023G1250	PARI LC SPRINT STAR Vernebler
023G1260	PARI LC SPRINT without PIF
023G3010	PARI BOY Pro Year Pack (DE/AT)
023G3011	PARI BOY Pro Year Pack (WE)
023G3016	PARI BOY Pro Year Pack (OE)
023G3019	PARI BOY SX / Pro Year Pack (Skan)
023G3210	PARI BOY Classic Year Pack (DE/AT)
023G3211	PARI BOY Classic Year Pack (WE)
023G3216	PARI BOY Classic Year Pack (OE)
023G3219	PARI TurboBOY / Classic Year Pack (Skan)
023G3310	PARI BOY Junior Year Pack (DE/AT)
023G3311	PARI BOY Junior Year Pack (WE)
023G3319	PARI JuniorBOY / Junior Year Pack (Skan)
023G3510	PARI COMPACT2 Year Pack
023G3511	PARI COMPACT2 Year Pack (Nordics)
023G3512	PARI COMPACT2 Year Pack (UK)
023G5800	PARI LC SPRINT CENTRAL
023G6001	LC SPRINT ohne Schlauch (Exp.)
023G6002	LC SPRINT STAR ohne Schlauch (Exp.)
023G6003	LC SPRINT Junior ohne Schlauch (Exp.)
023G6010	PARI LC SPRINT Klinikpackung
023G6011	PARI LC SPRINT Junior Klinikpackung
023G6012	PARI LC SPRINT STAR Klinikpackung
023G6015	PARI LC SPRINT SP Hospital Pack (Benelux)
023G6016	PARI LC SPRINT SP Klinikpackung 100er-Pack (de)
023G6018	PARI LC SPRINT SP Klinikpackung CENTRAL 100er-Pack (de)
023G6110	PARI LC SPRINT SP (FR)
023G6116	PARI LC SPRINT SP (WE)
023G8150	PARI LC SPRINT (AUS)
023G8181	PARI Verleihzubehörset 4plus S (de)
023G8740	PARI LC SPRINT STAR (AUS)

These articles are part of the following systems/ procedure packs:

Number	Name	Number of system/ procedure packs declaration
023G1120	PARI LC SPRINT Junior Package	023-Art22-001 (from rev. 023-Art22-001-002)
023G6120	PARI LC SPRINT SP with Child Mask (fr)	023-Art22-001 (from rev. 023-Art22-001-001)
023G6126	PARI LC SPRINT SP with Child Mask (WE)	
023G6130	PARI LC SPRINT SP with adult mask (FR)	
023G6136	PARI LC SPRINT SP with adult mask (WE)	
023G6150	PARI LC SPRINT SP BABY (FR)	
023G6151	PARI LC SPRINT SP BABY (Benelux)	
023G8180	PARI Verleihzubehörset BABY S	
130G1000	PARI BOY Pro Inhalation System (DE/AT)	130-ART22-001 (from rev. 130-ART22-001-001)
130G1001	PARI BOY Pro Inhalation System (WE)	
130G1012	PARI BOY Pro Inhalation System (JP)	
130G1017	PARI BOY Pro Inhalation System (KR)	
130G1200	PARI BOY Classic Inhalation System (DE/AT)	
130G1201	PARI BOY Classic Inhalation System (WE)	
130G1204	PARI BOY Classic Inhalation System (UK)	
130G1206	PARI BOY Classic Inhalation System (OE)	
130G1209	PARI BOY Classic Inhalation System (Skan.)	
130G1211	PARI BOY Classic Inhalation System (IL)	
130G1215	PARI BOY Classic Inhalation System (AUS/NZ)	
130G1300	PARI BOY Junior Inhalation System (DE/AT)	
130G1301	PARI BOY Junior Inhalation System (WE)	
130G1312	PARI BOY Junior Inhalation System (JP)	
152G1000	PARI COMPACT2 Inhalationssyst. (DE)	152-ART22-002 (from rev. 152-ART22-002-000)
152G1004	PARI COMPACT2 Inhalationssyst. (UK)	
152G1009	PARI COMPACT2 Inhalationssyst. (Nordics)	
152G1300	PARI COMPACT2 Junior Inhalationssys.(DE)	