



EC Declaration of Conformity for Medical Devices

In accordance with Annex II 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 adult mask soft
PARI child mask soft Spiggy**

**PARI baby mask soft
(Type 041)**

(Aerosol delivery mask for inhalation therapy)

GMDN Code: 35142

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 until a modification is necessitated by a conformity related change (resp. at the latest until May 26, 2024), whereupon a new conformity declaration will be issued.

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 11, 2021

Dr. Davia Viellechner
- President -



ID-Nr. 041-MDD-002-009

Attachment

This Declaration of Conformity is valid for the following configurations:

Number	Name
041E0740	PARI adult mask soft
041G0740	PARI adult mask soft
041E0741	PARI child mask soft Spiggy
041G0741	PARI child mask soft Spiggy
041E0743	PARI baby mask soft
041G0746	Kindermaske soft mit Stabilisator 5er P.
041G0747	Erwachsenmaske mit Stabilisator 5er P.
041G0750	PARI baby mask soft
041G0751	PARI baby mask soft with mask stabiliser
051G0740	VORTEX Adult Mask with Mask Connector
041G0743	PARI Erwachsenenmaske soft (RU)
041G0744	PARI Kindermaske soft "Spiggy" (RU)