



ID-Nr. 077-MDR-002-002

## EU Declaration of Conformity for Medical Devices

in accordance with Annex IX Chapters I and III  
of Medical Device Regulation (EU) 2017/745

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 NaCl 0.9% Inhalation solution (Type 077)

(PARI NaCl 0.9% inhalation solution is used to moisten the airways and as a secondary treatment for cold infections. It can also be used as a carrier solution for medications which, according to the manufacturer's instructions, may be diluted with isotonic saline solution for inhalation)

Basis-UDI-DI: 426002043-P077-0000-00NY

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

complies with the

Medical Device Regulation (EU) 2017/745 dated 25th May 2017.

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. G10 011861 0631 Rev. 02 (Expiry: 24.05.2026)

CE 0123

Starnberg, September 24<sup>th</sup>, 2025

A blue ink signature of Dr. Frank Bredl.

Dr. Frank Bredl  
- President -



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Attachment

This Declaration of Conformity is valid for the following configurations:

Number	Name
077G0000	PARI NaCl 0.9% Inhalation Solution 20x2,5ml
077G0001	PARI NaCl 0,9% 2x2,5 ml NaCl -Sample-
077G0003	PARI NaCl 0.9% Inhalation Solution 60x2,5ml
077G0006	PARI NaCl 0.9% Inhalation Solution 2x60x2,5ml
077G0008	PARI NaCl 0.9% NaCl Inhalationslösung 120x2,5ml (ECU)
077G0010	PARI NaCl 0.9% Inhalation Solution 10x5,0ml
077G0020	PARI NaCl 0.9% Inhalation Solution 20x5,0ml
077G0033	PARI NaCl 0.9% Inhalation Solution 30x3,0ml
077G0034	PARI NaCl 0.9% Inhalation Solution 30x4,0ml