

## **DECLARATION OF CONFORMITY**

We declare under our sole responsibility that

Medical Group: <u>CPAP/VPAP Nasal Mask and Accessories</u> Medical Device: <u>CPAP/VPAP Nasal Mask and Accessories</u>

Item Code: As Attachment

Classification: IIa

**( E** 2460

according to Rule 2 in annex IX of directive 93/42/EEC

meets the provision of the directive 93/42/EEC in consideration of the change of the directive 2007/47/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: Directive 93/42/EEC annex II, excluding section 4; the manufacturer is fully responsible for the content of declaration of conformity.

Registration No.: 10240-2017-CE-RGC-NA-PS

Notified Body: DNV GL Nemko Presafe A/S (notify body number – 2460)

Valid until: November, 12 2023

EU Rep: mdi Europa

Address: Langenhagener Strasse71, 30855 Langenhagen, Germany

Taichung, Feb 3, 2020

Place / Date

VP of Sales and Marketing



## Attachment of DoC

Product Section	Product Type
CPAP Nasal Mask	M-268010-12, M-268020-10, M-268020-11, M-268020-12,
	M-268020-13, M-268030-10, M-268030-11, M-268030-12,
	M-268030-13, M-268040-10, M-268040-11, M-268040-12,
	M-268040-13, M-268090-30, M-429400-13, M-429400-14,
	M-429400-15

