

DECLARATION OF CONFORMITY

We declare under our sole responsibility that

Medical Group: CPAP/VPAP Nasal Mask and Accessories

Medical Device: CPAP/VPAP Nasal Mask, Nasal Pillow Mask, NIPPV Tubing, and Connector

Item Code: As Attachment

Classification: IIa



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

The following standards are applied for all devices:

EN 1041:2008, EN ISO 14971:2019, EN ISO 10993-1:2018, EN ISO10993-5:2009, EN ISO10993-10:2013, EN ISO 13485:2016, EN 62366:2008, EN ISO 80369-7:2017, EN ISO 17510:2020, EN ISO 5356-1:2015

Taichung, Apr 22, 2021

Place / Date



VP of Sales and Marketing

Attachment of DoC

Product Section	Product Type	Customer Product No.
CPAP Nasal Mask	10253	00003440
	10254	00003434
	10255	00003435
CPAP Nasal Pillow Mask	11254	00003499
VPAP Nasal Mask	11353	00003486
	11354	00003487
	11355	00003488