

# DECLARATION OF CONFORMITY

We declare under our sole responsibility that  
Medical Group: CPAP/VPAP Face Mask and Accessories  
Medical Device: CPAP/VPAP Face Mask  
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

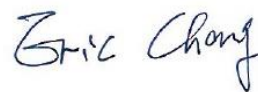
Address: Langenhagener Strasse 71, 30855 Langenhagen, Germany

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, Aug 12, 2021

*Place / Date*



*Eric Chang / General Manager*

**Attachment of DoC**

Product Section	Product Type	Customer Product No.	Brand
CPAP Face Mask	10211	00003438	HOFFRICHTER
		NA	Hsiner
	10217	00003461	HOFFRICHTER
		NA	Hsiner
	10227	00003462	HOFFRICHTER
		NA	Hsiner
	10243	00003441	HOFFRICHTER
		NA	Hsiner
	11343	00003483	HOFFRICHTER
		NA	Hsiner
	11344	00003484	HOFFRICHTER
		NA	Hsiner
	11345	00003485	HOFFRICHTER
		NA	Hsiner
	11311	00003489	HOFFRICHTER
		NA	Hsiner
	11312	00003490	HOFFRICHTER
		NA	Hsiner
	11313	00003491	HOFFRICHTER
		NA	Hsiner
10244	00003436	HOFFRICHTER	
	NA	Hsiner	
10245	00003437	HOFFRICHTER	
	NA	Hsiner	