Declaration of Conformity

MANUFACTURER

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AUTHORIZED REPRESENTATIVE:

Name: Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg，Germany
Tel: +49-40-2513175 Fax:+49-40-255726 E-mail：shholding@hotmail.com

MEDICAL DEVICE:

Venturi Mask

Model	Type	Size
Fixed Venturi Mask	General	XL/SXL/L/M/S/XS
	Tracheostomy	Adult/Pediatric
	O2 plus	Adult/Pediatric
Adjustable Venturi Mask	General	XL/SXL/L/M/S/XS
Multi-vent Venturi Mask	General	XL/SXL/L/M/S/XS
	Tracheostomy	Adult/ Pediatric
	O2 plus	Adult/Pediatric
Hyperbaric Oxygen Chamber Venturi Mask	/	Adult/ Pediatric/ Infant

UMDNS CODE: 12452

Classification: IIa (Rule two, Annex Ⅸ, MDD 93/42/EEC)
Conformity Assessment Procedure: Annex II

DIRECTIVES

We declare that the Venturi Mask is conform to the following Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC as amended by 2007/47/EC concerning medical devices.

Standard Applied: All applicable Harmonized EN Standards.
Notified Body: SGS Belgium NV
Address: SGS House Noorderlaan 87 2030 Antwerp Belgium

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Identification Number： CE 1639

(EC) Certificate(s): CN19/41067

Expire date of the Certificate: 2028-12-31

Date CE mark was affixed: 2009-09-19

Place, Date of Issue: 2024-02-23 / Ningbo

SIGNATURE : **NAME:** LINNA LUO/ Manager, QA Dept.

Add: No.138, BinHaisi Road, Hangzhou Bay New Zone, Ningbo City, Zhejiang Province, 315336, P.R.China

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Appendix

List of catalogue numbers

Medline Reference	Soundway Reference	
41098S	A0505	Venturi Mask
41088S	/	MASK,MULTI-VENT,7 ADJUSTABLE CONC,TBG STD,ADULT
41089S	/	MASK,MULTI-VENT,TBG STD,PED

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