Declaration of Conformity

MANUFACTURER

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Tel: +86-574-63269102/63006301 Fax:+86-574-63259048/63006305
http: www.soundway-medical.com

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:

Model Name	Type or Size
General Nebulizer Mask kit set (with vanilla or without vanilla)	XL/SXL/L/M/S/XS
General Nebulizer Mask without nose-clip kit set	Adult/Pediatric
O2 Plus Nebulizer Mask kit set	Adult/Pediatric
Tracheostomy Nebulizer Mask kit set	Adult/Pediatric
SJ face tent Mask kit set	Adult
Transverse Mask kit set	Adult/Pediatric
General Nebulizer Mask without Nebulizer connector kit set	XL/L/M/S
Mask only	General Nebulizer Mask only (with vanilla or without vanilla)
	General Nebulizer Mask without nose-clip only
	O2 Plus Nebulizer Mask only
	Tracheostomy Mask only
	SJ face tent Mask only
	Transverse Mask only
	General Nebulizer Mask without Nebulizer connector only
Nebulizer	2# / 4# / 4# alveolar / 5# / 11# / 12# / 13#

UMDNS CODE: 12449

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

Medical Device Directive:

COUNCIL DIRECTIVE DIRECTIVE 93/42/EEC of 14 June 1993
concerning medical devices.
Standard Applied: All applicable Harmonized EN Standards.
Notified Body: SGS Belgium NV
Address: SGS House Noorderlaan 87 2030 Antwerp Belgium
Identification Number: CE 1639
(EC) Certificate(s): CN19/41067
Expire date of the Certificate: 2024-03-08
Date CE mark was affixed: 2009-09-19
Place, Date of Issue: 2020-12-29 / 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

Appendix

List of catalogue numbers

Medline Reference	Soundway Reference	
1083S	A0241	Soundway Nebulizer Mask
41085S	A0243	Soundway Nebulizer Mask

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