Declaration of Conformity

Manufacturer

Name: Ningbo Shengyurui Medical Appliance Co., Ltd.

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

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: General Oxygen Mask with Reservoir Bag, O2 Plus Oxygen Mask with Reservoir Bag, Reservoir Bag(accessory)

Trade name: Non Rebreathing Mask, Rebreathing Mask

Type or size:

XL, SXL, L, M, S, XS (General Oxygen Mask with Reservoir Bag)

Adult/Pediatric (O2 Plus Oxygen Mask with Reservoir Bag)

UMDNS code: 12450

Classification: IIa (Rule two, Annex Ⅸ, MDD 93/42/EEC)

Conformity Assessment Procedure: Annex II (excluding section 4) of Directive 93/42/EEC as amended by 2007/47/EC

DIRECTIVES

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

Better breathing, Better life.

(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: 2021-06-03 / 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	Description
1059S	A0305	General Oxygen Mask with Reservoir Bag -XL
41007S	A0334	General Oxygen Mask with Reservoir Bag -M
41058S	A0307	General Oxygen Mask with Reservoir Bag -M
41060S	A0301	General Oxygen Mask with Reservoir Bag -XL
41069S	A0118	General Oxygen Mask with Reservoir Bag -L

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