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：Simple Oxygen Mask

Type or size:

General Oxygen Mask with vanilla (XL、SXL、L、M、S、XS)
General Oxygen Mask without vanilla (XL、SXL、L、M、S、XS)
General Oxygen Mask without nose-clip(Adult、Pediatric)
O_2 Plus Oxygen Mask(Adult、Pediatric)
Tracheostomy Oxygen mask (Adult、Pediatric)
SJ face tent oxygen mask(Adult)
Low Concentration Oxygen mask(XL、SXL、L、M、S)
Italy mask(Adult、Pediatric)

UMDNS code: 12448

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

We declare that the Simple Oxygen 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

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: 2020-12-22 / 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
1041S	A0101	General Oxygen Mask without vanilla - XL
1049S	A0109	General Oxygen Mask without vanilla - XL
41035s	A0104	General Oxygen Mask without vanilla - S
41040s	A0102	General Oxygen Mask without vanilla - L
41042s	A0103	General Oxygen Mask without vanilla - M
41050s	A0111	General Oxygen Mask without vanilla - M

www.soundway-medical.com
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Ningbo City, Zhejiang Province, China
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Fax: 86-574-63259048