Declaration of Conformity

MANUFACTURER

Name: Ningbo Shengyurui Medical Appliances Co., Ltd.

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AUTHORIZED REPRESENTATIVE:

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MEDICAL DEVICE:

Nasal Cannula

Model	Type	Size
Simple Nasal Cannula	Softplus/standard	Adult/pediatric/infant/ neonate/ preemie
High-flow Nasal Cannula	Softplus/standard	
Nasal cannula with extension tube	Softplus/standard	
Simple Nasal Cannula with humidifier	Softplus with humidifier/ standard with humidifier/ softplus with humidifier B/ standard with humidifier B	

UMDNS CODE:

Nasal Cannula ： 12700

Classification:

IIa (Rule Five, Annex Ⅸ, MDD 93/42/EEC)

Conformity Assessment Procedure:

Annex II

DIRECTIVES

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): CN 19/41067

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

Appendix

List of catalogue numbers

Medline reference	Description
1873CE	NASAL CANULA, SOFTECH PLUS, STAR TBG 210CM, NEONAT
1872CE	NASAL CANULA,SOFTECH PLUS,STAR TBG,INFANT
1870CE	NASAL CANULA,SOFTECH PLUS,STAR TBG 210CM,ADULT
1877CE	NASAL CANULA,SOFTECH PLUS,STAR TBG 420CM,ADULT
1871CE	NASAL CANULA, SOFTECH PLUS, STAR LUMEN 210CM, PED
1820CE	NASAL CANULA, SOFTECH,STAR LUMEN 210CM, ADULT
1826CE	NASAL CANULA, SOFTECH,STAR LUMEN 210CM, PED
1828CE	NASAL CANULA, SOFTECH, STAR LUMEN 210CM, INFANT
921010	NASAL CANNULA STAR LUMEN 30CM STD ADULT CURVED
1102P	Nasal cannula, Star Lumen tubing, Standard connector, Pediatric
1101P	Nasal cannula, Star Lumen tubing, Standard connector, Infant
1100P	Nasal cannula, Star Lumen tubing, Standard connector, Neonatal
1103P	Nasal cannula
1104P	NASAL CANNULA,FLARE
1105P	Nasal cannula, Star Lumen tubing, Standard connector, 4m Adult

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Table Harmonised Standards

Reference standard	Title of the standard
93/42/EEC(as amended by 2007/47/EC)	Medical Devices Directive
EN ISO13485:2016/A11:2021	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN ISO 14971:2019/A11:2021	Medical devices. Application of risk management to medical devices.
EN ISO10993-1:2020	Biological evaluation of medical devices —Part 1: Evaluation and testing within a risk management process
EN ISO10993-5:2009	Biological evaluation of medical devices —Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
EN ISO 10993-18-2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
EN ISO 18562-1:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
EN ISO 18562-2:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
EN ISO 18562-3:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
EN ISO 18562-4:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.
MEDDEV 2.7.1 Rev 4 2016	Medical devices directives clinical investigation-Clinical evaluation: Guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
EN 62366-1:2015/A1:2020	Medical devices – Application of usability engineering to medical devices
EN ISO 15001-2011	Anaesthetic and respiratory equipment Compatibility with oxygen
EN 13544-2:2002+A1:2009	Respiratory therapy equipment - Part 2 Tubing and connectors
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 80601-2-74:2021	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (ISO 80601-2-74:2021)
ISO 20789: 2018	Anaesthetic and respiratory equipment- Passive humidifiers
ASTM F 1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
EN ISO 23368-2022	Anaesthetic and respiratory equipment-Low flow nasal cannula

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