EC Certificate Full Quality Assurance System: CN09/21829

The management system of

Ningbo Shengyurui Medical Appliances Co., Ltd.

No. 138, Binhaisi Road, Hangzhou Bay New Zone,
315336, Ningbo, Zhejiang Province, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 May 2019 until 08 March 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 25 November 2021
Issue 14. Certified since 19 November 2009

Certification is based on reports numbered CN/NGB 5495

Authorised by

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Ningbo Shengyurui Medical Appliances Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 14

Detailed scope

**Sterile and non sterile Simple Oxygen Mask,
Sterile and non sterile Oxygen Mask with Reservoir Bag,
Sterile and non sterile Nebulizer Mask,
Sterile and non sterile Nasal Cannula,
Sterile and non sterile First Aid Mask,
Sterile and non sterile Venturi Mask,
Sterile and non sterile Medical Valves Series (including Three Way Stopcock, Sterile and non sterile Two Way Stopcock, Sterile and non sterile Three Way Stopcock with Extension Tube, Extension Tube),
Sterile and non sterile Suction Connection Tube with Yankauer Handle,
Sterile and non sterile Tracheostomy Mask,
Sterile and non sterile Jet Nebulizer Set,
Sterile and non sterile Anaesthetic Mask,
Sterile and non sterile Non invasive Positive Pressure Ventilation Mask,
Oxygen Flow Metering device,
Sterile and non sterile Capno CO_2 Mask,
Sterile and non sterile Capno CO_2 Nasal Cannula (including Capno O_2/CO_2 Nasal Cannula and Capno CO_2 Sampling Nasal Cannula),
Sterile and non sterile Two Way Manifold,
Sterile and non sterile Breathing Circuit (including Dual limb breathing circuit, Single limb breathing circuit, J circuit, Dual limb breathing circuit with catheter mount, and accessories of HME, HMEF, BV Filter, HEPA Filter),
Sterile and non sterile Electrostatic adsorption film Bacteria Filter (including BV Filter, PFT Filter, HMEF, HEPA Filter),
Sterile and non sterile Anaesthetic breathing circuit (including Circuit and accessories of Gas Sampling Line, BV Filter, Breathing Bag)**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market