SAFETY SYSTEM
YOUR PROTECTOR

DICHIARAZIONE DI CORRISPONDENZA

SIR SAFETY SYSTEM
S.p.A unipersonale
Soggetta a direzione
di SIR Holding S.r.l.

Sede Legale
Via dei Fornaciai, 9
06081 S.Maria degli Angeli
Assisi - Perugia - Italy

Partita IVA:
033 59 34 05 48

Telefono:
075 804.37.37 r.a.

Fax Commerciale:
075 804.37.47

Fax Amministrazione:
075 804.47.76

E-mail:
sir@sirsafety.com

Web Site:
www.sirsafety.com

Capitale Sociale:
Euro 3.500.000 i.v.

R.I. PG:
033 59 34 05 48

REA PG:
n° 28 36 20

Indirizzo PEC:
amm.ne@pec.sirsafety.com

Sede di Milano:
Viale Europa, 74
20090 Cusago (MI)

Telefono:
02 903.94.575 r.a.

Fax:
02 903.94.441

AZIENDA CON SISTEMA
DI GESTIONE PER LA QUALITÀ
CERTIFICATO
UNI EN ISO 9001:2015

La società:

SIR SAFETY SYSTEM SPA Unipersonale
Via dei Fornaciai, 9
06081 S.MARIA Degli ANGELI (PG)

Dichiara sotto la propria responsabilità, che il seguente Dispositivo:

MASCHERA DA RIANIMAZIONE BOCCA A BOCCA
Articolo **FH1233**

E' corrispondente all'articolo
CPR Masks (MS001)

Fabbricato da
Hangzhou Jinlin Medical Appliances Co.,Ltd

Indicato nella Dichiarazione allegata

S. MARIA DEGLI ANGELI 28/06/2023

Gino SIRCI
Amministratore Delegato
SIR SAFETY SYSTEM SPA UNIPERSONALE

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

Hangzhou Jinlin Medical Appliances Co., Ltd

M14-3-4,Hangzhou Ecomomic & Technological Development Zone Hangzhou 310018 Zhejiang China

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

CPR Masks

der Klasse: /
of class: /
de la classe: /
di classe:

class **IIa**

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Directive 93/42/EEC Annex II, excluding Section 4

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

HD 60140292 0001

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

杭州 2020.01.21

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60140292 0001

Report No.: 15077208 008

Manufacturer:
Hangzhou Jinlin
Medical Appliances Co., Ltd.
M14-3-4, Hangzhou Economic &
Technological Development Zone
Hangzhou
310018 Zhejiang
P.R. China

Products:
Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60118053 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-01-20

Date: 2020-01-20

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle
Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60140292 0001
Report No.: 15077208 008

Manufacturer:
Hangzhou Jinlin
Medical Appliances Co., Ltd.
M14-3-4, Hangzhou Economic &
Technological Development Zone
Hangzhou
310018 Zhejiang
P.R. China

Products:
- Tracheostomy Tubes
- Tracheal Tubes
- Stopcocks
- Suction Catheters
- Oxygen Masks
- Nasal Oxygen Cannulas
- Nebulizers
- Yankauer Suction Handles
- Extension Tubes
- Face Masks with Air Cushion
- CPR Masks
- Tracheostomy Masks
- Breathing Systems
- Disposable Anaesthesia Air Filters
- CVP Manometers

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Laryngoscope Blades

Date: 2020-01-20

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60140292 0001
Report No.: 15077208 008

Manufacturer:
Hangzhou Jinlin
Medical Appliances Co., Ltd.
M14-3-4, Hangzhou Economic &
Technological Development Zone
Hangzhou
310018 Zhejiang
P.R. China

Site included:

No.18th, Guiling Road, Xuancheng Economic and Technological Development Zone, Anhui Province, China

Notified Body

Date: 2020-01-20

TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierungsstelle

Fuxiu Sheng III