DNV·GL

EC CERTIFICATE

Production Quality Assurance

Certificate No.:	Project No.:	Valid Until:
9822-2017-CE-RGC-NA-PS Rev. 2.0	PRJC-80015-2008-PRC-CHN	27 May 2024

This is to certify that the quality system of:

Changshu Taining Medical Equipment Co., Ltd.

Nan Shou, Yangyuan Town, Changshu City, Jiangsu Province, P. R. China

For production and final product inspection/testing of:
STERILE DISPOSABLE MEDICAL DEVICE

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX V OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 16 October 2020

Digitally signed by Belan Irina
Date: 2021.09.10 16:06:07 EEST
Reason: MoldSign Signature
Location: Moldova

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Alessandra Rinna

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	**Description**	**Issue Date**
0.0	Replaces the certificate 7544-2015-CE-RGC-NA Rev. 0.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460)	2017-08-19
1.0	Recertification	2020-10-09
2.0	**Editorial change**	2020-10-16

Products covered by this Certificate:

Product Description	**Product Name**	**Class**
Rectal Tube	F24, F26, F28, F30, F32, F34, F36	IIa
Suction Catheter	F5, F6, F8, F10, F12, F14, F16, F18, F20, F22	IIa
Oxygen Mask	Large, Medium, Small	IIa
Nelaton Catheter	F6, F8, F10, F12, F14, F16, F18, F20, F22, F24	IIa
Feeding Tube	F4, F5, F6, F7, F8, F10, F12, F14, F16, F18, F20, F22	IIa
Nasal Oxygen Cannula	Large, Medium, Small	IIa
Endotracheal Tube	F8(2.0), F10(2.5), F12(3.0), F14(3.5), F16(4.0), F18(4.5), F20(5.0), F22(5.5), F24(6.0), F26(6.5), F28(7.0), F30(7.5), F32(8.0), F34(8.5), F36(9.0), F38(9.5), F40(10.0), F42(10.5), F44(11.0)	IIa
Stomach Tube	F4, F5, F6, F7, F8, F10, F12, F14, F16, F18, F20, F22, F24	IIa
Mucus Extractor	F6, F8, F10, F12, F14, F16	IIa
Feeding Set	Gravity A, Gravity B (500ml, 1000ml, 1200ml, 1500ml. 2000ml) Pump A, Pump B (500ml, 1000ml, 1200ml, 1500ml, 2000ml)	IIa

The complete list of devices is filed with the Notified Body

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Sites covered by this certificate

Site Name	Address
Changshu Taining Medical Equipment Co., Ltd.	Nan Shou, Yangyuan Town, Changshu City, Jiangsu Province, P. R. China

EU Representative
MedNet **EC-REP** GmbH, Borkstrasse 10, 48163 Münster, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate