Wenzhou Longde Medical Technology Co toodetud autoklaav ei vasta EL-i nõuetele

Terviseamet annab teada, et Wenzhou Longde Medical Technology Co toodetud autoklaavi sertifikaat on võltsitud, seadme deklaratsioonis on valeandmed ning eeltoodust tulenevalt ei vasta seade Euroopa Liidu nõuetele.

Sellele tootjale ei ole väljastatud sertifikaate NB 0123 ja NB 1023 ning vastavusdeklaratsioonil nimetatud asutus ei ole tootjast teadlik ja on terviseametile kinnitanud, et neil puudub igasugune seos sellise toote ja ettevõttega Wenzhou Longde Medical Technology Co.

Tulenevalt võltsitud sertifikaadist ja vastavusdeklaratsioonist, on ka tootel olev CE märk alusetult paigaldatud ning sellist autoklaavi ei tohi kasutada.

Wenzhou Longde Medical Technology Co toodetud autoklaavi ostnutel soovitab terviseamet kaup müüjale tagastada.

Täiendava teabe saamiseks pöörduge terviseameti meditsiiniseadmete osakonna poole mso@|terviseamet.ee

Võltsitud vastavussertifikaat

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 01 02894 002

Manufacturer:
Wenzhou Longde Medical Technology Co., Ltd.
A Building,No 158,Gaoyi Road,Hi-tech Industrial Development Zone,Wenzhou,Zhejiang

EC-Representative:
MDS Medical Limited
93 Headlands
Kettering
Northamptonshire NN 15 5EG
UNITED KINGDOM

Product Category(ies):
Pressure Steam Sterilizer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH17115801

Valid from: 2018-03-27
Valid until: 2023-03-26

Date, 2018-03-27

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 01 02894 002

Facility(ies):

Wenzhou Longde Medical Technology Co.,Ltd.
A Buliding,No 158,Gaoyi Road,Hi-tech
Industrial Development Zone,Wenzhou,zhejiang
PEOPLE'S REPUBLIC OF CHINA

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A1 / 07.17

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WENZHOU LONGDE MEDICAL TECHNOLOGY CO., LTD.
A Building,No 158,Gaoyi Road,Hi-tech Industrial Development Zone,Wenzhou,Zhejiang
TEL:+86-577-89615525
E-mail:sales@chinalongde.com
www.chinalongde.en.alibaba.com

Declaration of Conformity

Manufacture: **Wenzhou Longde Medical Technology Co.,Ltd.**
Address: A Building,No 158,Gaoyi Road,
Hi-tech Industrial Development Zone,Wenzhou,Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **MDS MEDICAL LIMITED**
93 headlands,kettering, Northamptonshire, NN15 5EG, United Kingdom

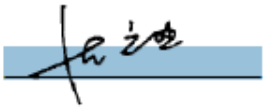
Product Category: Pressure Steam Sterilizer
Models: AM-BAS-12L, AM-BAS-18L, AM-BAS-22L, AM-PRE-12L, AM-PRE-18L, AM-PRE-22L, AM-COMP-8L

Classification: IIb based on MDD 93/42/EEC annex IX rule15
The GMDN code: 38671
Conformity Assessment Route: Annex II.3

We declare the compliance of the above medical device with the applicable requirements of Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC. All the supporting documents and files are retained under the premises of the manufactures.
The manufacturer is fully responsible for all of this Declaration.

Notified Body: **TÜV SÜD Product Service GmbH**
Ridlestrasse. 65,80339 München, Germany.
Identification number: 0123
Certificate: NO. G1 18 01 02894 002
Expire date of the Certificate: 2023-03-26
Start of CE-Marking: 2018-03-27

Place, Date of Issue: Zhejiang, Mar 27th, 2018

Signature: 

Name: Yuanye Shen
Position : General manager