EC CERTIFICATE

Number: 6061308CE01

Full Quality Assurance System

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

Manufacturer:

Hangzhou Jimushi Meditech Co., Ltd.

Building 1, No.2628 Yuhang Tang Road
Cangqian Street, Yuhang District
311121 Hangzhou
China

For the product category(ies)

Sterile urethral catheter for single use for Intermittent catheterization

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 6058179CN, initially dated 7 April 2020
Addendum, initially dated 7 April 2020

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 7 April 2020
Revised: 1 May 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 6061308CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Sterile urethral catheter for single use for Intermittent catheterization

Issued to:

Hangzhou Jimushi Meditech Co., Ltd.
Building 1, No.2628 Yuhang Tang Road
Cangqian Street, Yuhang District
311121 Hangzhou
China

This certificate covers the following product(s):

- Sterile urethral catheter for single use

Initial date: 7 April 2020
Revision date: 1 May 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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