EC CERTIFICATE

Number: 6054198CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V

(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Changzhou Shuangma Medical Devices Co., Ltd.

San He Kou Development Zone, Zhenglu, Tianning
213115 Changzhou, Jiangsu
China

For the product category(ies)

Non-active Device for Injection, Infusion, Gynecological Examination, Urinary Collection Bags, Medical Face Masks

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 6054198CN, initially dated 03 September 2019
Addendum, initially dated 03 September 2019

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 the manufacture and final inspection, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex V Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory.
The necessary information related to the quality assurance 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: 03 September 2019
Revised: 28 July 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 6054198CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Non-active Device for Injection, Infusion, Gynecological Examination, Urinary Collection Bags, Medical Face Masks

Issued to:

Changzhou Shuangma Medical Devices Co., Ltd.
San He Kou Development Zone, Zhenglu, Tianning
213115 Changzhou, Jiangsu
China

This certificate covers the following product(s):

- Sterile Syringes for Single Use (class IIa)
- Sterile Infusion Sets for Single Use (class IIa)
- Sterile Burette Infusion Sets for Single Use (class IIa)
- Sterile Hypodermic Needles for Single Use (class IIa)
- Gynecological Sets (class IIa)
- Cervical Samplers (class IIa)
- Urinary Collection Bags for Single Use (class I sterile)
- Vaginal Speculums for Single Use (class I sterile)
- Medical Face Masks (class I sterile)

Initial date: 03 September 2019
Revision date: 28 July 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396