

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, Zhenglou, 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

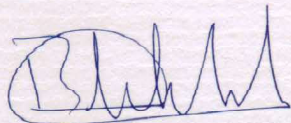
Documents, that form the basis of this certificate:

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

© Integral publication of this certificate and adjoining reports is allowed

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

1/1

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

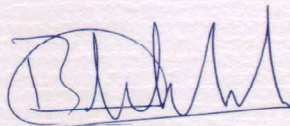
This certificate covers the following product(s):

- 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

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EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Name and address of the manufacturer: Changzhou Shuangma Medical Devices Co.,Ltd
San He Kou Development Zone, Zhenglu, Tianning, Changzhou City

SRN: CN-MF-000009732

Trademark: 

Name and address European Representative: Llins Service & Consulting GmbH
Heinigstrasse 26, 67059 Ludwigshafen, Germany

SRN: DE-AR-000009077

Product Name: Vaginal Speculums for Single Use

Product Model: Side screw type, Spanish type, French type

Basic UDI-DI: 69451447006KZQ6T

EMDN Code: U089006

Classification acc. to MDR Annex VIII: Class Is, rule 5

Applied Standard: EN ISO 14971:2019; EN ISO 10993-1:2020
EN ISO 20417: 2021; EN ISO15223-1:2021
EN ISO 13485:2016;

Conformity assessment procedure: Annex XI of Regulation EU 2017/745(MDR)

CE certificate no.: /

Issue date: /

Valid until: /

Name, address and ID of the Notified Body: DEKRA Certification B.V.
Meander 1051, 6825 MJ Arnhem, P.O. Box 5185, 6802 ED Arnhem, The Netherlands

CE 0344

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Changzhou, 2023-06-03

Changzhou, 2023-06-03

Place, date

Xu Aiping, General manager

Xu Aiping, General manager

Name and function



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

Your ref.
Our ref. MED/24-7387380
Tel. +31 88 96 83 009
Fax +31 88 96 83 100
E-mail medical.nl@dekra.com

Arnhem, 7 February 2024

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement (dated 8 May 2023) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Changzhou Shuangma Medical Devices Co., Ltd.
San He Kou Development Zone, Zhenglu,
Tianning, 213115 Changzhou, Jiangsu,
China
SRN Number: CN-MF-000009732

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement

concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,



Ms. Xiaoli Ren
Project Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Syringes for Single Use	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Sterile Infusion Sets for Single Use	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Sterile Burette Infusion Sets for Single Use	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Sterile Hypodermic Needles for Single Use	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Cervical Samplers	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Vaginal Speculums for Single Use	Class Is	N/A	Certificate # 6054198CE01; NB# 0344

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2024-02-07	6048800CN07.1	Initial issue