Declaration of Conformity

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

Authorized European Representative: Llins Service & Consulting GmbH
Obere Seegasses 34/2, 69124, Heidelberg, Germany

PRODUCTS:

Product Name	Product Number	Description	GMDN Code	Classification
Sterile Syringes for Single Use	1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL, 60mL	Syringes	63095	Class IIa; Annex IX, Rule 6

CONFORMITY ASSESSMENT ROUTE: MDD Annex V

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED: Applied standards are listed in the Essential Requirements Checklist

NOTIFIED BODY: DEKRA Certification B.V.
Meander 1051
6825 MJ Arnhem
P.O. Box 5185
6802 ED Arnhem
The Netherlands

Notified body number: 0344

EC CERTIFICATE: 6054198CE01

DESIGN EXAMINATION CERTIFICATE: N/A

START OF CE MARKING:

Product Name	Product Number	Date of First CE Marking	First Batch Manufactured under Current Notified Body Number
Sterile Syringes for Single Use	1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL, 60mL	03 September 2019	2019-8

PLACE, DATE OF ISSUE: Changzhou, 01 November 2019

SIGNATURE:

Mr. Guolin FENG
General Manager
For and on behalf of
Changzhou Shuangma
Medical Devices Co., Ltd.

Ms. Aiping XU
QMR
For and on behalf of Changzhou
Shuangma Medical Devices Co., Ltd.