

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

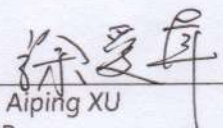
START OF CE MARKING:

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.