JIANGSU JIANZHIYUAN MEDICAL INSTRUMENTS TECHNOLOGY CO., LTD.
Floor 2, Building102, No.198, East Wuzhou Road, Development Zone, 225000 Yangzhou, PRC

Declaration of conformity

1. Manufacturer

Manufacturer name: JIANGSU JIANZHIYUAN MEDICAL INSTRUMENTS TECHNOLOGY CO., LTD.

Manufacturer address: Floor 2, Building102, No.198, East Wuzhou Road, Development Zone, 225000 Yangzhou, People's Republic of China

2. EC-representative

Name: ZOUSTECH S.L.
Address: Pso. Castellana, 141 - Planta 19, 28046 - Madrid, Spain
Tel: +34694426446 Fax: +34917915466 E-mail: legal@zoustech.eu

3. Product name: Chest Drainage Catheter for Single Use

4.Model: WI,WII,WIII,ZI,ZII,ZIII

5. UMDNS Code of product: 10685
6. Classification of product: MDD93/42/EEC Class IIa (Rule 6)
7. Conformity assessment route: MDD93/42/EEC Annex V.3

8. We declare:

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives. All supporting documentations are retained under the promises of the manufacturer.
JIANGSU JIANZHIYUAN MEDICAL INSTRUMENTS TECHNOLOGY CO., LTD. is exclusively responsible for the declaration of conformity.

9. We follow the applicable directives include:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

10. Notified body

Notified Body name: TUV SUD Product Service GmbH
Notified Body address: Ridlerstr65 Munich 80339, Germany
Identification number: 0123

Identification number: 0123
CE-Certificate No.: G2 002901 0002 Rev. 00
Valid until :2024-05-26
CE-marking starting batch or date: 2019-10-21

Signature of issuing person: _____
Name: Hongyan Liu
Title: General Manager

JIANGSU JIANZHIYUAN MEDICAL INSTRUMENTS TECHNOLOGY CO.,LTD. 江苏健之缘医疗器械科技有限公司

Digitally signed by Morozov Maria
Date: 2023.09.19 10:59:58 EEST
Reason: MoldSign Signature
Location: Moldova

Digitally signed by Palii Nina
Date: 2024.09.20 12:45:08 EEST
Reason: MoldSign Signature
Location: Moldova
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