EC Declaration of Conformity

Manufacturer:

WAYSON MEDICAL CO., LTD.

Add.: No.81, Junfeng Road, Huangpu, 510760, Guangzhou, China

whose single Authorized Representative:

SHANGHAI INTERNATIONAL HOLDING CORP. GMBH(EUROPE). Add: EIFFESTRASSE 80, 20537 HAMBURG, GERMANY

We, the manufacturer, herewith declare that the products

WOUND DRESSING

UMDNS-Code: 10-276

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IS according to Annex IX of the Directive 93/42/EEC.

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany Certificate No.: DD 60131187 0001 Issue date: 12.11.2018

Expiry date: 07.08.2023

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

Application of the abovementioned Annexes and the intervention by the Notified Body is limited to:

The aspects of manufacture concerned with securing and maintaining sterile conditions.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: WAYSON MEDICAL CO., LTD.

Address: No.81, Junfeng Road, Huangpu, 510760, Guangzhou, China

<u>Guangzhou, 2020.11.4</u> Place, date General Manager