EC Declaration of Conformity

Manufacturer:

Yangzhou Medline Industry Co., Ltd.
No. 108, Jinshan Road, Economic Development Zone, Yangzhou, 225009, Jiangsu, China

whose single Authorized Representative:

Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse 80,20537 Hamburg, Germany
(Tel: 049-40-2513175; Fax: 049-40-255726)

We, the manufacturer, herewith declare that the products
SCALP VEIN SET
Size: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G

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

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and 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 assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: DD 60149237 0001
Issue date: 2020-05-11
Expiry date: 2028-12-31

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

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

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

Company: Yangzhou Medline Industry Co., Ltd.
Address: No. 108, Jinshan Road, Economic Development Zone, Yangzhou, 225009 Jiangsu, P.R.China

Site included: No.1, Huafa Road, Development Zone, Yangzhou, Jiangsu 225000, China

YANGZHOU MEDLINE INDUSTRY CO., LTD.

Yangzhou, 11th, May, 2020 — Tanwei, Quality Manager
Place, date — *Legally binding signature, Function*