EC Declaration of Conformity

Manufacturer:

Shandong Kangli Medical Equipment Technology Co., Ltd.
No. 206 National Road, Shizhong District, Zaozhuang City, Shandong Province, 277117 China

whose single Authorized Representative:

Lotus Global Co., Ltd
1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG United Kingdom
Tel:+0044-20-75868010
Fax:+0044-20-79006187
Email: peter@lotusglobaluk.com

We, the manufacturer, herewith declare that the products

Ostomy collection bags
Model:One-Piece Close Pouch One-Piece Drainable Pouch
Two-Piece Close Pouch Two-Piece Drainable Pouch
One-Piece Urostomy Pouch Two -Piece Urostomy Pouch

UMDNS-Code: 16-459

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

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

CE

The product concerned has been designed and manufactured under a quality management system according EN ISO 13485:2012 and EN ISO 13485:2012/AC 2012.

Compliance of the designated product with the Annex VII of Directive 93/42/EEC has been assessed and set out the EC Declaration of Conformity.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

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Zaozhuang April 17, 2018
Place, date

Linzhuang
Legally binding signature, Function

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Q/KL-CE- OCB - 05 A