

EC Declaration of Conformity

Manufacturer:

Jiangsu Province Huaxing Medical Apparatus
Industry Co.,Ltd.
No.328, Tongda Road, Touqiao Town, Guangling
District, City of Yangzhou, Jiangsu Province, China

whose single Authorized Representative:

AKUS Innovation in Anaesthesia S.L. San
Antonio 15, 4B, 30001 Murcia (Spain)

We, the manufacturer, herewith declare that the products

Anaesthesia needle for single use

Item No.: SW20092-19, SQ20092-19, SW20110-19, SQ20110-19, SW20120-19, SQ20120-19, SQ20092, SQ20110, SQ20120, SW22092-19, SQ22092-19, SW22110-19, SQ22110-19, SW22120-19, SQ22120-19, SQ22050, SQ22092, SQ22110, SW23092-19, SQ23092-19, SW23110-19, SQ23110-19, SQ23050, SQ23092, SQ23110, SW25050-21, SQ25050-21, SW25092-21, SQ25092-21, SW25110-21, SQ25110-21, SW25126-21, SQ25050, SW25126, SW26092-21, SQ26092-21, SW26110-21, SQ26110-21, SW27050-21, SW27092-21, SQ27092-21, SW27110-21, SQ27110-21, SW27126, SW27126-21, EP16080TU, EP16095TU, EP18050TU, EP18080TU, EP18095TU, EP20050, EP20080, EP20095, EP22050, EP22080, EP22095, BN21050, BN21070, BN21090, BN21140, BN22050, BN22070, BN22090, BN22140, BN21050US, BN21070US, BN21090US, BN21140US, BN22070US, BN22090US, BN21050PRO, BN21070PRO, BN21090PRO, BN21140PRO, BN22050PRO, BN22070PRO, BN22090PRO, BN21090EC090, BN21140EC110, CNB22090-19, CNB22070-19.

GMDN-Code: 58293;

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

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



The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC as modified by 2007/47/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
Registration No.: HD60148620 0001

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC as modified by 2007/47/EEC.

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

Jiangsu Province Huaxing Medical Apparatus Industry Co.,Ltd.

No.328, Tongda Road, Touqiao Town, Guangling District, City of Yangzhou, Jiangsu Province, China

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Legally binding signature, Function

management representative

ruyong liu