Declaration of Conformity

Manufacturer
Name: JIANGSU KANGBAO MEDICAL EQUIPMENT CO., LTD.
Address: 78#, North Suzhong Road, Baoying, Yangzhou, Jiangsu Province, P. R. China

European Representative
Name: **Shanghai International Holding Corp. GmbH(Europe)**
Address: Eiffestrasse 80,20537 Hamburg Germany

Product: DOLPINA enterale Spritze ENFit®

Models and specifications：

20ml - REF D20ML1 (single unit), REF D20ML30 (box of 30 units)

60ml - REF D60ML1 (single unit), REF D60ML30 (box of 30 units)

100ml - REF D100ML1 (single unit), REF D100ML30 (box of 30 units)

Classification: I Sterile, rule 2

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directive and Standards (MDD/93/42/EEC). The products meet prospective uses and all supporting documentation are retained under the premise of manufacturer and the Notified body. we are exclusively responsible for this DoC.

Directives

General Applicable Directive: MDD 93/42/EEC
Standard: All applicable harmonized standard

Notify Body: TÜV SÜD Product Service GmbH, Ridlerstr.65, D-80339 Munich, Germany

NB ID：0123

CE Certificate NO: G2S 050970 0015

CE Certificate issuing date: 2019-06-26

CE Certificate expiry date: 2023-05-27

Place, Date: Jiangsu, Baoying, 2019-10-14

Name: Liu Hui

Signature:

Position: Managing Director

Date: 2019-10-14

JIANGSU KANGBAO MEDICAL EQUIPMENT CO.,LTD. 江苏康宝医疗器械有限公司

EC Declaration of Conformity

Manufacturer:

Jiangsu Micsafe Medical Technology Co., Ltd
Address: Xituan Industrial Park, Dafeng District, Yancheng, 224125, Jiangsu, China

whose single European Representative:

Share Info Consultant Service LLC Repräsentanzbüro
Address: Heerdter Lohweg 83, 40549 Düsseldorf

We, the manufacturer, herewith declare that the following products:

Product	OEM Ref.	Capacity	Ref., models, and specifications:
DOLPINA enterale Spritze ENFit zur Medikamentengabe	ER01ST	1 mL	REF D1ML1 (single unit), REF D1ML30 (box of 30 units)
	ER025ST	2.5 mL	REF D3ML1 (single unit), REF D3ML30 (box of 30 units)
	ER05ST	5 mL	REF D5ML1 (single unit), REF D5ML30 (box of 30 units)
	ER10ST	10 mL	REF D10ML1 (single unit), REF D10ML30 (box of 30 units)

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

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

CE 0197

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

Compliance of the designated product with the Directive 93/42/EEC aspects of manufacture concerned with securing and maintaining sterile conditions 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 60147126 0001

Issue date: 2020.05.03

Expiry date: 2024.05.26

following the procedure relating to the EC Declaration of Conformity set out in Annex IX of the 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: Jiangsu Micsafe Medical Technology Co., Ltd
Address: Xituan Industrial Park, Dafeng District, Yancheng, 224125, Jiangsu, China

YANCHENG / 2023.05.12
Place and Date

江苏迈硕医疗科技有限公司
JIANGSU MICSAFE MEDICAL TECHNOLOGY CO.,LTD

DRONA DONG / QA MANAGER
PRRC Signature and Position