01 Declaration of Conformity

Manufacturer :

Name : Ningbo Luke Medical Devices Co.,Ltd.

Add : Gujiayan, Yangming Road, 315400 Yuyao City, Zhejiang Province, People's Republic of China

Tel:+86-574-22661850 Fax:+86-574-22661880

European Representative :

Name :Shanghai International Holding Corp.GmbH(Europe)

Add : Eiffestrasse 80 ,20537 Hamburg , Germany

Tel:+49-40-2513175 Fax:+49-40-255726

Production Name: Drainage Bag

Object of the Declaration:

1000ml	DB11000A

UMDNS Code :11301

Classification (MDD, Annex IX) : Is

Classification and relevant Rule of MDD 93/42/EEC: Annex IX, Rule 1

Conformity Assessment Route : Annex V.3 of MDD 93/42/EEC

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General Applicable Directives:

Medical Device Directive : COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device(MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Notified Body : TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany

Identification Number : CE0123

(EC) Certificate(s) :GCQ 086250 0024 Rev. 00(CL 086250 0025 Rev. 01)

Expire Date of the Certificate : 2028-12-31

Start of CE Marking : 2016-11-04

Position : General Manager

Name : Cheng Liu

Place, Date of Issue :Yuyao, 2024-09-12

Signature: Cheng Liu 2024.09.12