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
European Representative :
Name :Shanghai International Holding Corp.GmbH(Europe)
Add : Eiffestrasse 80 ,20537 Hamburg , Germany
Tel:+49-40-2513175 Fax:+49-40-255726

Product Name : Drainage bag
Object of the Declaration : DB-1000
UMDNS Code : 11301
Classification (MDD, Annex IX) : I sterile
Classification and relevant Rule of MDD 93/42/EEC: Annex V, 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) : G2S 086250 0019 Rev.01
Expire Date of the Certificate : 2024-05-26
Start of CE Marking : Not mark till now
Place, Date of Issue :Yuyao
Signature: Yehua Zhang 2020.01.11
Name : Yehua Zhang
Position : **General Manager**