Nipro Medical(Hefei) Co., Ltd.
Office: +86-551-68795000Fax: +86-551-68795008
Address: No.350, Yungu Road, Economic & Technological Development Zone, Hefei, 230601, China

Declaration of Conformity

Manufacturer:
Name: NIPRO MEDICAL (HEFEI) CO., LTD.
Add: NO.350, YunguRoad, Economic &Technological Development Zone Hefei, 230601 CHINA

Tel: +86-551-68795000 Fax: +86-551-68795008

European Representative:
Name:NIPRO MEDICAL EUROPE
(NaamlozeVennootschap)
Add: Blokhuisstraat 42, 2800 Mechelen, BELGIUM

Product Name:Synthetic Hemodialyzer

Classification and relevant Rule of MDD: **Ⅱb MDD 93/42/EEC as amended by2007/47/ECAnnex IX, Rule 3**

Types/Sizes: ELISIO-M series, ELISIO-H series, ELISIO-K series, ELISIO-L series
ELISIO-13M,ELISIO-15M,ELISIO-17M,ELISIO-19M,ELISIO-21M
ELISIO-13H,ELISIO-15H,ELISIO-17H,ELISIO-19H,ELISIO-21H
ELISIO-13K,ELISIO-15K,ELISIO-17K,ELISIO-19K,ELISIO-21K
ELISIO-13L,ELISIO-15L,ELISIO-17L,ELISIO-19L,ELISIO-21L

Digitally signe
Date: 2022.03.
Reason: MoldS
Location: Mol

The UMDNS code: 11234
Product Certification Conformity Assessment Route: Annex Ⅱ.3 of MDD 93/42/ECas amended by2007/47/EC

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)as amended by2007/47/EC
Standard: *See TDH-001-06 "List of applicable Standards"*

Notified Body: SGS Belgium NV,
Noorderlaan 87, 2030 Antwerpen, Belgium

Your Partner in Health Care
Nipro Medical(Hefei) Co., Ltd.
Office: +86-551-68795000Fax: +86-551-68795008
Address: No.350, Yungu Road, Economic & Technological Development Zone, Hefei, 230601, China

Identification Number: 1639

CE Certificate No.: CN19/41138

Valid until: 12/03/2022

Date CE mark was affixed: 16 /12/ 2019

Signature of issue person: Tadahiro Goto

Position: Plant Manager

Tadahiro Goto

Date: 2020-1-07