



**Nipro Medical(Hefei) Co., Ltd.**

Office: +86-551-68795000 Fax: +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: **II b 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

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



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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*

*Date: 2020-1-07*