NIPRO

Date: December 23, 2021

To whom it may concern,

DECLARATION

We, NIPRO CORPORATION, hereby declare that the attached documents are true and complete copies of EC certificate for following medical device(s).

Medical Device(s):

SYNTHETIC HEMODIALYZER
ELISIO-09H, 11H, 13H, 15H, 17H, 19H, 21H, 25H
ELISIO-11M, 13M, 15M, 17M, 19M, 21M
ELISIO-11L, 13L, 15L, 17L, 19L, 21L
ELISIO-11HX, 13HX, 15HX, 17HX, 19HX, 21HX

HEMODIALYZER
FB-05U, 07U, 09U, 11U, 13U, 15U, 17U, 19U, 21U

HEMODIALYZER
SUREFLUX-05E, 07E, 09E, 11E, 13E, 15E, 17E, 19E, 21E

SAFETOUCH DIALYSIS CATH
14Gx4/5", 14Gx1", 14Gx1-1/4", 14Gx1-1/2"
15Gx1", 15Gx1-1/4", 15Gx1-1/2"
16Gx1", 16Gx1-1/4", 16Gx1-1/2"
17Gx1", 17Gx1-1/4", 17Gx1-1/2"

NIPRO ULTRAFILTER
CF-609N

Sincerely yours,

M. Otani

OTANI Miho,
Manager,
Medical Regulatory Affairs Department,
Quality Assurance & Regulatory Compliance Headquarters
NIPRO CORPORATION

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 043398 0275 Rev. 01

Manufacturer:

Nipro Corporation
3-9-3, Honjo-Nishi, Kita-ku
Osaka 531-8510
JAPAN

Product Category(ies): **Hemodialyzers, Hemofilters, Balloon Infusers, Endotoxin Filter, Huber Needles/Huber Needle Sets, Intravenous Catheters, Stopcocks, Biohole Kit, Hemodialysis Catheter, Hemoconcentrators, Hemodiafilters**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JNQ235037648**

Valid from: **2019-10-31**
Valid until: **2024-05-26**

Date, **2019-11-04**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 043398 0275 Rev. 01

Facility(ies):

Nipro Corporation
3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, JAPAN

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

Product Service

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

Nipro Corporation

3-9-3, Honjo-Nishi, Kita-ku
Osaka 531-8510 Japan

Munich, 2021-01-05
Order No.: 713205007_2

Confirmation concerning EC Certificate G1 043398 0275 Rev. 01

We confirm that the following certificate:

G1 043398 0275 Rev. 01 (valid until 2024-05-26)

issued to the legal medical device manufacturer:

Nipro Corporation
3-9-3, Honjo-Nishi, Kita-ku,
Osaka 531-8510
JAPAN

covers the Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) with the scope:

Hemodialyzers, Hemofilters, Balloon Infusers, Endotoxin Filter, Intravenous Catheters, Stopcocks, Biohole Kit, Hemodialysis Catheter, Hemoconcentrators, Hemodiafilters

With this letter we confirm that the above products are manufactured at:

Nipro Corporation Odate Factory
8-7, Hanukiyachi, Niida, Odate-shi, Akita, 018-5794 JAPAN

Only the facility which is covered by the QMS of the manufacturer can be listed on the EC certificate issued by TÜV SÜD Product Service GmbH. Nipro Corporation Odate Factory is not listed on the certificate G1 043398 0275 Rev. 01 because Nipro Corporation and Nipro Corporation Odate Factory maintain their own individual QMS.

Product Service

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificate is valid.

R. Köhler

i.A. Randolf Köhler
TÜV SÜD PRODUCT SERVICE GMBH
Medical Health Services
Foreign Affairs

Registered No. 2535 −2021

NOTARIAL CERTIFICATE

This is to certify that Mr. ITO Hisayuki an agent of Ms. OTANI Miho, Manager, Medical Regulatory Affairs Department, Quality Assurance & Regulatory Compliance Headquarters of NIPRO CORPORATION has stated in my very presence that said Ms. OTANI Miho acknowledged herself to have signed to the attached document.

Dated this 28th day of December, 2021

Shunji Tamaki

TAMAKI Shunji

Notary
Osaka Legal Affairs Bureau
1-2, Hirano-Machi, 2-Chome,
Chuo-ku, Osaka, Japan

OSAKA LEGAL AFFAIRS BUREAU
NOTARY
1-2, HIRANO-MACHI, 2-CHOME,
CHUO-KU, OSAKA JAPAN

令和　3　年登簿第　2535　号
認　　証

嘱託人　ニプロ株式会社
信頼性保証本部　メディカル薬事部　課長　大谷美穂は、
代理人　井東久幸によって、当公証人の面前で、この
証書の署名を自認した。

よって、これを認証する。
令和 3 年　12月　28　日、本公証人役場において
大阪市中央区平野町2丁目1番2号
大阪法務局所属
公証人
Notary
玉置俊二
TAMAKI Shunji

総公証　No. 112351　号

証　　明

上記署名は、大阪法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。
令和 3 年　12 月　28　日

大阪法務局長　末永雅之

CERTIFICATE

This is to certify that the signature affixed above has been provided by Notary, duly authorized by the Osaka Legal Affairs Bureau and that the Official Seal appearing on the same is genuine.

Date　DEC. 2 8. 2021

SUENAGA Masayuki
Director of the Osaka Legal Affairs Bureau

For legalization by the foreign consul in Japan, this is to certify that the Seal affixed hereto is genuine.

Date　DEC. 2 8. 2021

福谷佳津美

Osaka, FUKUTANI Katsumi
Official
Ministry of Foreign Affairs
(Consular Service Division)

ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN
EMBASSY OF THE S.R. OF VIET NAM IN JAPAN
CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: VIỆT NAM
   Country: Viet Nam

   Giấy tờ, tài liệu này
   This public document

2. Do ông (bà): **FUKUTANI KATSUMI** ký
   Has been signed by
3. Với chức danh: CÔNG CHỨC
   Acting in the capacity of *OFFICIAL*
4. Và con dấu của BỘ NGOẠI GIAO NHẬT BẢN
   Bears the seal/stamp of: *MINISTRY OF FOREIGN AFFAIRS OF JAPAN*

được chứng nhận/hợp pháp hóa lãnh sự
Certified

5. Tại: Tô-ki-ô
   At: Tokyo
6. Ngày: 06/01/2022
   The (dd/mm/yyyy)
7. Cơ quan cấp: ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN
   By EMBASSY OF THE S.R. OF VIET NAM IN JAPAN
8. Số: **02-01C/HPHLS**
   N°

KT. Đại sứ/On behalf of the Ambassador
Công sứ/Minister

LÂM THỊ THANH PHƯƠNG