

Date: October 20, 2021

To: Ministry of Health (Department of Medical Equipment and Construction)

LETTER OF AUTHORIZATION

We, NIPRO CORPORATION, 3-9-3, Honjo-Nishi, Kita-Ku, Osaka 531-8510, JAPAN, as the product owner of the medical devices do hereby authorize:

NIPRO SALES VIETNAM COMPANY LIMITED

Address: Floor 15, Unit 15.06 &15.07, Viettel Complex Building, 285 Cach Mang Thang 8, Ward 12, District 10, Ho Chi Minh City, Vietnam

To marketing the following medical devices in Vietnam.

Name of Products:

As attached list on page 2/4 and 4/4

We commit to provide and support all information concerning the product information, product quality upon request by Vietnam Ministry of Health (Department of Medical Equipment and Construction) for medical devices mentioned above.

This Authorization Letter is valid until 20 October, 2026.

Legal representative of the product owner

M. Otani

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

List of products

NIPRO CORPORATION ODATE FACTORY	
8-7, Hanukiyachi, Niida, Odate-shi, Akita, 018-5794 JAPAN	
Product Names	Models/ Sizes
SAFETOUCH PLUG IV Connector	ST-P
SAFELET CATH	14Gx2", 16Gx1 1/4", 16Gx1 1/2", 16Gx2", 16Gx2 1/2", 18Gx1", 18Gx1 1/4", 18Gx1 1/2", 18Gx2", 18Gx2 1/2", 20Gx1", 20Gx1 1/4", 20Gx1 1/2", 20Gx2", 22Gx1", 22Gx1 1/4", 24Gx3/4", 24Gx1"
NIPRO STOPCOCK	3W-R-L
SUREFUSER+	SFS-0505HRP, SFS-0512HRP, SFS-0501DP, SFS-0502DP, SFS-0503DP, SFS-0505DP, SFS-0501WP, SFS-1030MP, SFS-1001HRP, SFS-1005HRP, SFS-1012HRP, SFS-1001DP, SFS-1036HRP, SFS-1002DP, SFS-1003DP, SFS-1005DP, SFS-1001WP, SFS-1-15P, SFS-2-15P, SFS-3-15P, SFS-3.5-15P, SFS-250-25P, SFS-125-25P, SFS-62.5-25P, SFS-10-25P, SFS-5-25P, SFS-3.5-25P, SFS-2-25P, SFS-1.5-25P, SFS-2-30P, SFS-3-30P, SFS-4-30P, SFS-5-30P, SFS-6-30P, SFS-8-30P, SFS-1001DPUV, SFS-1002DPUV, SFS-10-25PUV, SFS -5-25PUV, SMA-0123-10P, SMA-2345-10P, SMA-123-10P, SMA-2345-25P, SMA-2468-25P, SMA-3456-25P, SMA-2435-30P, SMA-3456-30P, SMA-2468-30P
SUREFUSER+ PCA SET	P0530/S0504DP, P2030/S1002DP, P3030/S4-30P, P3060/S4-30P, P3030/M2345-30P
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"
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 CORPORATION ODATE FACTORY	
8-7, Hanukiyachi, Niida, Odate-shi, Akita, 018-5794 JAPAN	
Product Names	Models/ Sizes
SYNTHETIC HOLLOW FIBER DIALYZER	ELISIO-110HR, 130HR, 150HR, 170HR, 190HR, 210HR ELISIO-110LR, 130LR, 150LR, 170LR, 190LR, 210LR
SYNTHETIC HEMODIALYZER	ELISIO-11HX, 13HX, 15HX, 17HX, 19HX, 21HX ELISIO-09H, 11H, 13H, 15H, 17H, 19H, 21H, 25H ELISIO-11M, 13M, 15M, 17M, 19M, 21M ELISIO-11L, 13L, 15L, 17L, 19L, 21L
HEMODIALYZER	FB-05U, 07U, 09U, 11U, 13U, 15U, 17U, 19U, 21U
HEMODIALYZER	SUREFLUX-05E, 07E, 09E, 11E, 13E, 15E, 17E, 19E, 21E
NIPRO ULTRAFILTER	CF-609N
BRIZIO HEMOCONCENTRATOR	BHC 030G, BHC 110G

NIPRO MEDICAL INDUSTRIES LTD. Tatebayashi Plant	
2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518 JAPAN	
Product Names	Models/ Sizes
NIPRO DENTAL NEEDLE	27Gx21mm, 27Gx30mm, 30Gx21mm
NIPRO SPINAL NEEDLE	16G(1.65mm)x88mm, 18G(1.25mm)x88mm, 19G(1.05mm)x88mm, 20G(0.90mm)x88mm, 21G(0.80mm)x88mm, 22G(0.70mm)x88mm, 23G(0.63mm)x88mm, 25G(0.50mm)x88mm, 26G(0.46mm)x88mm, 27G(0.41mm)x88mm

LIBATAPE PHARMACEUTICAL CO., LTD. KUMAMOTO SECOND FACTORY	
1039-5, Sozaki, Shichijyo-machi, Kikuchi-shi, Kumamoto, 861-1344 JAPAN	
Product Names	Models/ Sizes
NIPRO SAFE DERM	10 μ m 5 \times 7cm, 10 μ m 8 \times 12cm, 10 μ m 10 \times 15cm, 30 μ m 5 \times 7cm, 30 μ m 8 \times 12cm, 30 μ m 10 \times 15cm, 30 μ m 12 \times 25cm
NIPRO SAFE FIX IVN	30 μ m 6 \times 6cm, 30 μ m 7 \times 10cm, 30 μ m 10 \times 12cm



Shibuya Corporation

2-232, Wakamiya, Kanazawa-shi, Ishikawa-ken, 920-0054 JAPAN

Shibuya Corporation Medical Equipment Wakamiya Factory

2-72, Wakamiya, Kanazawa-shi, Ishikawa-ken, 920-0054 JAPAN

Product Names	Models/ Sizes
SINGLE PATIENT DIALYSIS MACHINE	SURDIAL 55Plus
SINGLE PATIENT DIALYSIS MACHINE	NCU-18

YAC ELEX Co., Ltd.

Medical Device Manufacturing Center

1-36, 2-Chrome, Sumida, Higashi-Osaka-shi, Osaka, 578-0912 JAPAN

Product Names	Models/ Sizes
SINGLE PATIENT DIALYSIS MACHINE	DIAMAX
SINGLE PATIENT DIALYSIS MACHINE	DIAMAX WOW

Nipro (Thailand) Corporation Limited

10/2 Moo 8, Bangnomko, Sena, Phra Nakhon Si Ayuthaya 13110, THAILAND

Product Names	Models/ Sizes
NIPRO STERILE SYRINGE FOR SINGLE USE WITHOUT NEEDLE DOESAVER LD	1mL LUER SLIP
NIPRO STERILE SYRINGE FOR SINGLE USE WITH NEEDLE DOESAVER ND	1mL 25G x 1"



Registered No. 2036 - 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 22nd day of October, 2021





TAMAKI Shunji

Notary

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





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 10 月 22 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. 104375 号

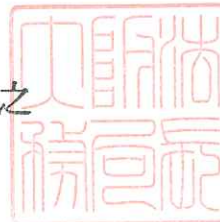
証 明

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 10 月 22 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 OCT. 22. 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 OCT. 22. 2021

福谷 佳津美

FUKUTANI Katsumi

Osaka,

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: **26/10/2021**
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: **01-03D/HPHLS**
Nº

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



LÂM THỊ THANH PHƯƠNG