

Date: October 4, 2021

To whom it may concern,

DECLARATION

We, NIPRO CORPORATION, hereby declare that the attached document is a true and complete copy of ISO13485 certificate for NIPRO CORPORATION ODATE FACTORY.

Sincerely yours,

M. Otani

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



Product Service

Certificate

No. Q5 043398 0289 Rev. 01

Holder of Certificate: NIPRO CORPORATION



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

Facility(ies):

NIPRO CORPORATION ODATE FACTORY
8-7, Hanukiyachi, Niida, Odate-shi, Akita, 018-5794 JAPAN

See scope of certificate

Certification Mark:



Scope of Certificate:

Design and Development, Production, Sterilization (EO, gamma and e-beam), Packaging, and Distribution of Sterile and Non-sterile Single Use Medical Products for Blood Sampling, Hemodialysis, Infusion, Injection, Perfusion, Plasmapheresis, Transfusion, Cardiovascular, Vascular, and ART (Assisted Reproductive Technology), Caps for the Application of Pharmaceutical Products, In-Vitro Diagnostic Kits for Biochemistry, Immunology and Genetics. The provision of Medical Grade Silicone for Needle

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_043398_0289_Rev._01

Report No.: JN1648867

Valid from: 2021-09-01

Valid until: 2024-08-31

Date, 2021-09-01

Christoph Dicks
Head of Certification/Notified Body



Registered No. 1931 -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 7th day of October, 2021


TAMAKI Shunji



Notary

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





令和 3 年 登簿第 1931 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 7 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. 104333 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 7 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. 7. 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. 7. 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: **11/10/2021**
The (dd/mm/yyyy)
7. Cơ quan cấp: ĐÀI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI NHẬT BẢN
By **EMBASSY OF THE S.R. OF VIET NAM IN JAPAN**
8. Số: **01-01G/HPHLS**
Nº

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



LÂM THỊ THANH PHƯƠNG