



NIPRO CORPORATION
3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, JAPAN
TEL: +81-6-6372-2331 FAX: +81-6-6371-7422

Date: October 18, 2018

To whom it may concern;

DECLARATION

We, Nipro Corporation, hereby declare that the attached documents are true and complete copies of EC certificate.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'M. Doimoto', written over a horizontal dashed line.

Minoru Doimoto,
Deputy General Manager,
Quality Assurance & Regulatory
Compliance Division
NIPRO CORPORATION



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 18 01 43398 275

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



EC-Representative: **NIPRO MEDICAL EUROPE**
(Naamloze Vennootschap)
Blokhuisstraat 42,
2800 Mechelen,
BELGIUM

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.: JNQ235032810

Valid from: 2018-05-22

Valid until: 2021-11-05

Date, 2018-05-22

Stefan Preiß



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

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No. G1 18 01 43398 275

Facility(ies):

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認 証 証 書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



Japan

TÜV SÜD Japan Ltd. Sumitomo Fudosan Bldg. No.4 8F Shinjuku-ku Tokyo 160-0023 Japan

**Choose certainty.
Add value.**

Nipro Corporation

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

Japan, 2018-05-24

To Whom It May Concern

We, TÜV SÜD Japan Ltd. confirm that the following certificate:

G1 18 01 43398 275 (Valid until 2021-11-05)

issued to the following auditee:

Nipro Corporation

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

covers a full quality assurance system according to Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III):

**Hemodialyzers, Hemofilters, Balloon Infusers,
Endotoxin Filter, Huber Needles/Huber Needle Sets,
Intravenous Catheters, Stopcocks, Biohole Kit,
Hemodialysis Catheter, Hemoconcentrators,
Hemodiafilters**

With this letter, TÜV SÜD Japan Ltd. confirms 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 18 01 43398 275, because Nipro Corporation and Nipro Corporation Odate Factory maintain their own individual QMS.

TÜV SÜD Japan Ltd.
Noriyuki Ohta

Non Active Medical Products Manager
MHS Division



Telephone: +81 3 3372 4821
Telefax: +81 3 3372 4837
<http://www.tuv-sud.jp>

TÜV SÜD Japan Ltd.
Sumitomo Fudosan Bldg. No.4 8F
4-33-4 Nishi-Shinjuku
Shinjuku-ku Tokyo 160-0023 Japan

TÜV®



Registered No. 1299 - 2018

NOTARIAL CERTIFICATE

This is to certify that Mr. Naoto TERADA an agent of Mr. Minoru DOIMOTO, Deputy General Manager, Quality Assurance & Regulatory Compliance Division of NIPRO CORPORATION has stated in my very presence that said Mr. Minoru DOIMOTO acknowledged himself to have signed to the attached document.

Dated this 23rd day of October, 2018

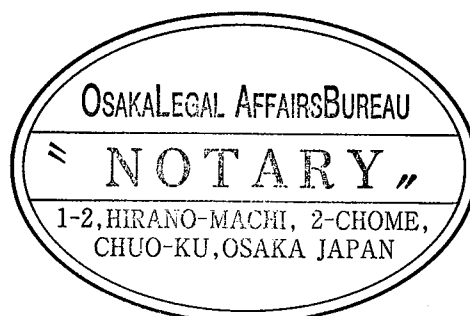
Shunji Tamaki

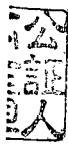


SHUNJI TAMAKI

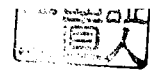
Notary

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





平成 30 年登簿第 1299 号
認 証



嘱託人 ニプロ株式会社
信頼性保証部 部長 土居本 稔 は、
代理人 寺田 尚人 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。

平成30年 10月23日、本公証人役場において

大阪府中央区平野町2丁目1番2号

大阪法務局所属

公証人

Notary

玉置 俊二

Shunji TAMAKI



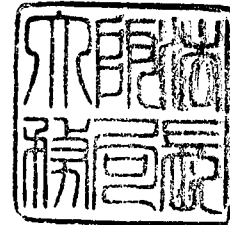
証 明

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。

平成30年 10月23日

大阪法務局長

杉浦 徳宏



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN

This public document

2. has been signed by Shunji TAMAKI

3. acting in the capacity of Notary of the Osaka Legal Affairs Bureau

4. bears the seal/stamp of Shunji TAMAKI, Notary
Certified

5. at Osaka

6. OCT. 23, 2018

7. by the Ministry of Foreign Affairs

8. 18-No. 002944

9. Seal/stamp:

10. Signature



Naomi Asano

Naomi ASANO

For the Minister for Foreign Affairs