



NIPRO CORPORATION  
3-9-3 Honjo-Nishi, Kita-ku, Osaka, Japan  
Phone: (06)6372-2331 · Fax: (06)6371-7422

Date: August 7, 2015

To whom it may concern;

**DECLARATION**

We, Nipro Corporation, hereby declare that the attached document is true and complete copy of ISO certificate.

Sincerely yours,

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

Minoru Doimoto,  
Deputy General Manager,  
International QA/RA section,  
Quality Assurance & Regulatory  
Compliance Division  
NIPRO CORPORATION





Product Service

# CERTIFICATE

No. **Q1N 15 03 44936 008**Holder of Certificate: **NIPRO MEDICAL INDUSTRIES LTD.****Tatebayashi Plant**

2-19-64, Matsubara

Tatebayashi-shi, Gunma

374-8518 JAPAN

Facility(ies):

NIPRO MEDICAL INDUSTRIES LTD. Tatebayashi Plant  
2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518  
JAPAN

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of  
Single Use Sterile and Non-Sterile Medical Products  
for Blood Sampling, Transfusion, Injection and Infusion  
and Hydrophilic GuidewireApplied  
Standard(s):EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

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). See also notes overleaf.

Report No.:

JNQ235017551

Valid from:

2015-08-01

Valid until:

**2018-07-31**

Hans-Heiner Junker

Date, 2015-08-03

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Registered No. 1292 - 2015

NOTARIAL CERTIFICATE

This is to certify that Mr. Hisayuki ITO an agent of Mr. Minoru DOIMOTO, Deputy General Manager, International QA/RA section, 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 12th day of August, 2015

*Rikio Udagawa*



RIKIO UDAGAWA

Notary

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







平成 27 年登簿第 1292 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  
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。

平成 27 年 8 月 12 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

宇田川 力雄



Rikio UDAGAWA

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 27 年 8 月 12 日

大阪法務局長

富田 一彦



## APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN

This public document

2. has been signed by Rikio UDAGAWA

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

4. bears the seal/stamp of Rikio UDAGAWA, Notary  
Certified

5. at Osaka

6. AUG. 12, 2015

7. by the Ministry of Foreign Affairs

8. 15-No. 001540

9. Seal/stamp:

10. Signature



Naomi ASANO

Naomi ASANO

For the Minister for Foreign Affairs