



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



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 0279 Rev. 01

Manufacturer:

Nipro Corporation

3-9-3, Honjo-Nishi, Kita-ku

Osaka 531-8510

JAPAN

Product Category(ies): Packed Needles, PSV Sets, AVF Needles, Blood Lines,
I.V. Catheters, Syringes with Needles,
Blood Collection Sets

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,

2019-10-31

Christoph Dicks

Head of Certification/Notified Body



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Facility(ies):

Nipro Corporation

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

+

Registered No.

2673 -2019

NOTARIAL CERTIFICATE

This is to certify that, as a result of checking at my office the attached copy of document with its original submitted by Mr. Hisayuki ITO.

I have found that the copy exactly corresponds with the original.

Dated this 16th day of December, 2019


SHUNJI TAMAKI



NOTARY

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



公証人 井 東 久 幸 の提出したこの
嘱託書 本は その原本と対照し符合すること
を認めた。

よって、これを認証する。

令和元年 12月 16 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。

令和元年 12月 16 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. DEC. 16. 2019

7. by the Ministry of Foreign Affairs

8. 19-No 009032

9. Seal/stamp:

10. Signature



Naomi ASANO

Naomi ASANO

For the Minister for Foreign Affairs