

CERTIFICATE

No. Q5 17 12 43398 274

Holder of Certificate: Nipro Corporation

NIPRO

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

Osaka 531-8510

JAPAN

Facility(ies): Nipro Corporation

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

JAPAN

Nipro Corporation Laboratory

3023 Noji, Kusatsu-shi, Shiga 525-0055,

JAPAN

Certification Mark:



Scope of Certificate: Design and Development,

Manufacture, Distribution of Machinery for Injection,

Infusion, Intervention and Artificial Organs

(including Accessories),

Disposable Medical Devices and Medicine Containers

465776723961

and In-Vitro Diagnostic Kits for

Biochemistry, Immunology and Genetics

Applied

EN ISO 13485:2016

Standard(s):

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). See also notes overleaf.

Report No.:

JNQ235031776

Valid from:

2018-03-01

Valid until:

2021-02-28

2018-03-01 Date,

Stefan Preiß

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