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

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 279 (Valid until 2022-10-13)

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):

Packed Needles, PSV Sets, AVF Needles, Blood Lines,
I.V. Catheters, Syringes with Needles, Blood Collection Sets

With this letter, TÜV SÜD Japan Ltd. confirms that the above products are manufactured at:

Nipro (Thailand) Corporation Limited
10/2 Moo 8 Bangnomko, Sena, Phra Nakhon Si
Ayutthaya 13110, THAILAND

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 (Thailand) Corporation Limited is not listed on the certificate G1 18 01 43398 279, because Nipro Corporation and Nipro (Thailand) Corporation Limited maintains their own individual QMS.

TÜV SÜD Japan Ltd.
Noriyuki Ohta

Non Active Medical Products Manager
MHS Division

TÜV SÜD JAPAN LTD.

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