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

TÜV SÜD 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 080998 0017 Rev. 00

Manufacturer:

NIPRO INDIA CORPORATION PVT. LTD.
Plot No. E-1/1, Khandala PH-I Industrial
Area, Taluka-Khandala
District-Satara
412 802 Maharashtra
INDIA

Product Category(ies):

Sterile Dialyzers,
Sterile Hypodermic Syringes with Needles,
Sterile Arterial Venous Fistula Needles,
Sterile I.V Cannulae and Sterile Blood Tubing 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.: IND2019114

Valid from: 2020-03-17
Valid until: 2024-05-26

Date, 2020-03-17

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 080998 0021 Rev. 00

Manufacturer:

NIPRO INDIA CORPORATION PVT. LTD.
Plot No. E-1/1
Khandala PH-I Industrial Area
District - Satara,
Taluka - Khandala,Maharashtra 412 802
INDIA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G1 080998 0017 Rev. 00

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply.

Report No.: IND2022078

Valid until: 2024-05-26

Issue Date: 2022-08-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 080998 0021 Rev. 00

Product Category(ies): Sterile Dialyzers,
Sterile Hypodermic Syringes with Needles,
Sterile Arterial Venous Fistula Needles,
Sterile I.V. Cannulae and Sterile Blood Lines.

Description of Change: Change of product category name, from "Sterile Blood Tubing Sets" to "Sterile Blood Lines".

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

NIPRO INDIA CORPORATION PVT. LTD.
Khandala PH-I Industrial Area
Plot No. E-1/1
District - Satara,
412 802 TALUKA - KHANDALA,MAHARASHTRA
INDIA

Your reference/letter of	Our reference/name	Tel. extension/Email	Date	Page
080998	TPS2974	medical_devices@tuvsud.com	2024-05-14	1 of 4

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 080998 0022 Rev. 00

Reference: TPS2974

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: IN-MF-000038605

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 080998 0022 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-14

TÜV SÜD Product Service GmbH
Medical and Health Services

Keyur Baruwala
Project Handler (PH)

TÜV SÜD Product Service GmbH
Medical and Health Services

Franziska Eckert
2024.05.14
16:05:17 +02'00'

Franziska Eckert
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **SYNTHETIC HEMODIALYZER** **BASIC UDI-DI: 4968420TD1011QV (High Flux)**	☒ **Class IIb**	☒ **N/A**	☒ **Certification as follows:** Certificate # G1 080998 0017 Rev. 00; NB# 0123
Device 2 **SYNTHETIC HEMODIALYZER** **BASIC UDI-DI: 4968420TD1012QX (Medium Flux)**	☒ **Class IIb**	☒ **N/A**	☒ **Certification as follows:** Certificate # G1 080998 0017 Rev. 00; NB# 0123
Device 3 **SYNTHETIC HEMODIALYZER** **BASIC UDI-DI: 4968420TD1013QZ (Low Flux)**	☒ **Class IIb**	☒ **N/A**	☒ **Certification as follows:** Certificate # G1 080998 0017 Rev. 00; NB# 0123
Device 4 **GENERAL-PURPOSE SYRINGE WITH NEEDLE** **BASIC UDI-DI: 4968420TD1041R6**	☒ **Class IIa**	☒ **N/A**	☒ **Certification as follows:** Certificate # G1 080998 0017 Rev. 00; NB# 0123
Device 5 **A.V. FISTULA NEEDLE** **BASIC UDI-DI: 4968420TD1031R3**	☒ **Class IIa**	☒ **N/A**	☒ **Certification as follows:** Certificate # G1 080998 0017 Rev. 00; NB# 0123
Device 6 **IV CANNULA WITH INJECTION PORT & WING** **BASIC UDI-DI: 4968420TD1021QY**	☒ **Class IIa**	☒ **N/A**	☒ **Certification as follows:** Certificate # G1 080998 0017 Rev. 00; NB# 0123
Device 7 **SYRINGE** **BASIC UDI-DI: 4968420TD1042R8**	☒ **Class Is+Im**	☒ **N/A**	☒ **Certification as follows:** Certificate # G1S 080998 0018 Rev. 00; NB# 0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
-	-	-	-

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-14	TPS2974	Initial issue

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under ~~Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or~~ Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	NIPRO INDIA CORPORATION PVT. LTD.
Manufacturer address and contact details	Plot No. E-1/1, Khandala PH-I Industrial Area, Taluka-Khandala, District-Satara, 412 802 Maharashtra, INDIA
Single Registration Number (SRN) (if available)	IN-MF-000038605

Authorised Representative name (if applicable)	NIPRO MEDICAL EUROPE
Authorised Representative address and contact details	Blokhuisstraat 42, 2800 Mechelen, BELGIUM
Single Registration Number (SRN) (if available)	BE-AR-000022416

Notified body name (if applicable)	■ See attached schedule
Notified body number (if applicable)	■ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	■ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	■ See attached schedule
End date of extended validity/transition period	■ See attached schedule

We, as the manufacturer declare under our sole responsibility:

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ ~~Expired *before* 20 March 2023:~~

  ☐ ~~Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or~~

  ☐ ~~A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or~~

  ☐ ~~A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)~~

  ~~*Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:*~~

  ☐ ~~Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.~~

  ☐ ~~We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.~~

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

✓ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

✓ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ ~~We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.~~

➢ ~~**Upclassified devices**~~

~~In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:~~

~~*Choose one applicable statement:*~~

☐ ~~Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.~~

☐ ~~We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.~~

➢ **Quality Management System (QMS)**

Choose one applicable statement:

✓ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ ~~QMS in accordance with Article 10(9) MDR is in place.~~

☐ ~~A notified body has issued the attached certificate for the MDR compliant QMS.~~

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD 93/42/EEC.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name	**NIPRO INDIA CORPORATION PVT. LTD.**
Location & Date	**Plot No. E-1/1, Khandala PH-I Industrial Area, Taluka-Khandala, District-Satara, 412 802 Maharashtra, INDIA, 15 May 2024**
Signature, Print Name, Title	田畑 浩次 **Tahata Koji, General Manager QA & QC**
Contact Details (at least email)	fda@niproindia.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
SYNTHETIC HEMODIALYZER	G1 080998 0017 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	2028-12-31	Not applicable
GENERAL-PURPOSE SYRINGE WITH NEEDLE	G1 080998 0017 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	2028-12-31	Not applicable
A.V. FISTULA NEEDLE	G1 080998 0017 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	2028-12-31	Not applicable
IV CANNULA WITH INJECTION PORT & WING	G1 080998 0017 Rev.00	2024-05-26	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	2028-12-31	Not applicable

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)