NIPRO INDIA CORPORATION PRIVATE LIMITED
Factory & Corporate Office : Plot No. E-1/1, Khandala Phase - 1 Industrial Area, Taluka - Khandala,
Dist. Satara - 412 802. Tel. : +91 2162 357200, Fax : +91 2162 357245

Declaration of Conformity

Manufacturer Name / Address	: Nipro India Corporation Pvt. Ltd. Plot No.E-1/1, Khandala PH-I Industrial area, Tal- Khandala, District- Satara, 412 802, Maharashtra, INDIA.
European Representative Name /Address	: Nipro Medical Europe (Naamloze Vennootschap) Blokhuisstraat 42, 2800 Mechelen, BELGIUM
Products	: Sterile I.V.Cannulae
Brand	: NIPRO WING CATH
Models	: 16G, 18G, 20G, 22G, 24G
Classification	: Class IIa according to MDD Annex IX Rule 7
Conformity Assessment Route	: MDD Annex II.3

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT MEETS THE PROVISION OF COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION SHALL BE RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

WEHEREWITH DECLARE THAT AS THE MANUFACTURER OF ABOVE MENTIONED PRODUCT "WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY".

Standard Applied	: As per attached Annexure-01
Notified Body and Identification Number	: TUV-SUD Product Service GmbH, 0123 Zertifizierstelle Ridlerstrasse 65, 80339, Muchen, Germany
EC Certificate No. and valid until	: G1 080998 0017 Rev. 00 valid till 2024-05-26
Start of CE Marking	: Device Manufactured from December-2013
Place/ date of issue this declaration of Conformity	: Nipro India Corporation Pvt. Ltd. Khandala, India, 2021-12-10
Signature	:
Name / Designation	: Vivek Deshpande – Dy. General Manager QA/QC

NIPRO INDIA CORPORATION PVT. LTD. KHANDALA, SATARA 412802

NIPRO
Your Partner in Health Care

NIPRO INDIA CORPORATION PRIVATE LIMITED

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ANNUXURE-01

DECLARATION OF CONFORMITY

Sr. No.	Standard Number	Standard Name
01	EN ISO 10555-1:2013 +A1:2017	Intravascular catheters. Sterile and single-use catheters - General requirements
02	EN ISO 10555-5:2013	Intravascular catheters. Sterile and single-use catheters - Over-needle peripheral catheters
03	EN ISO13485: 2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
04.	EN ISO 14971:2019	Medical devices -- Application of risk management to medical devices
05	ISO 80369-7:2016	Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic application
06	ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
07	ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
08	ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
09	EN ISO 11137-1:2015 +A2:2019	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
10	EN ISO 11137-2:2015	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
11	ISO 11137-3:2017	Sterilization of health care products -- Radiation -- Part 3: Guidance on dosimetric aspects of development, validation and routine control
12	EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
13	MDD –93/42/EEC-2007/47/EC	Council directive 93/42/EEC of 14 June 1993 Concerning medical devices
14	MEDDEV 2.7/1 Rev. 4	Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC
15	MEDDEV 2.12/2 Rev.02	Post market clinical follow-up studies- A guide for manufacturers and notified bodies
16	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
17	EN ISO 10993-1:2020	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

CIN : U33110PN2010FTC143058

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E-mail : indiaho@niproindia.com
Website : www.niproindia.com

Sr. No.	Standard Number	Standard Name
18	EN ISO 10993-4:2017	Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
19	ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
20	EN ISO 10993-10:2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
21	EN ISO 10993-11:2018	Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity
22	ISO 2859-4:2020	Sampling procedures for inspection by attributes - Procedures for assessment of declared quality levels
23	ISO 11737-1: 2018	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
24	ISO 11737-2:2020	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

NIPRO INDIA CORPORATION PVT. LTD. KHANDALA, SATARA 412802

Signature
Name / Designation

Mr. Vivek Deshpande
Deputy General Manager QA/QC