NIPRO

DECLARATION OF CONFORMITY

Manufacturer's name: Nipro Corporation

Manufacturer's address: 3-9-3, Honjo-Nishi, Kita-ku, Osaka 531-8510, JAPAN

European Representive's name: NIPRO MEDICAL EUROPE

European Representive's address: Blokhuisstraat 42, 2800 Mechelen, BELGIUM

Name of device(s) (Classification)
Packed Needles (IIa), PSV Sets(IIa), AVF Needles(IIa), Blood Lines(IIa), I.V. Catheters(IIa), Syringes with Needles(IIa), Blood Collection Sets (IIa)

Description of Device(s): See attachments

We hereby ensure and declare that the device(s) concerned meet(s) the provisions of the MDD 93/42/EEC.

This declaration is supported by:

EC quality system approval statement (Annex II excluding 4) No. G1 043398 0279 Rev. 01 issued by TUV SUD Product Service GmbH (ID No.0123), Ridlerstr. 65, D-80339 München, Germany on 31 October 2019.

In addition, manufacturer is exclusively responsible for this declaration of conformity.

Place: Osaka, Japan

Kazuhiko Hirata (Signature)
Manager
Medical Regulatory Affairs Department,
Quality Assurance & Regulatory Compliance Headquarters
(Position)

Date: 7 November 2019

Attached: Attachment 1-7

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Attachment 1-1

Description of Packed Needles (IIa)

Gauge	Type of bevel			Needle length (inch)									Sterilization method
	RB	SB	Blunt	1/2	5/8	3/4	7/8	1	1 1/4	1 1/2	2	2 3/4	
16	✓	-	-	-	-	-	-	✓	-	✓	-	-	EOG
18	✓	✓	✓	-	-	-	-	✓	✓	✓	✓	-	
19	✓	-	-	-	-	-	-	✓	✓	✓	✓	-	
20	✓	-	-	-	-	-	-	✓	-	✓	✓	✓	
21	✓	-	-	-	✓	-	-	✓	✓	✓	✓	✓	
22	✓	-	-	-	✓	✓	-	✓	✓	✓	✓	-	
23	✓	-	-	-	✓	-	-	✓	✓	✓	-	-	
24	✓	-	-	-	-	-	-	✓	✓	-	-	-	
25	✓	-	-	✓	✓	✓	-	✓	✓	✓	-	-	
26	✓	-	-	✓	-	-	✓	-	-	-	-	-	
27	✓	-	-	✓	-	✓	-	-	✓	✓	-	-	
28	-	-	✓	-	-	-	-	✓	-	-	-	-	
29	✓	-	-	✓	-	-	-	-	-	-	-	-	
30	✓	-	-	✓	-	-	-	-	-	-	-	-	