

**NIPRO**

Your Partner in Health Care

PT. NIPRO INDONESIA JAYA

Jl. Surya Utama Kav. I - 22B, 23 & 24 Kawasan Industri Surya Cipta,
Desa Kutamekar, Kecamatan Ciampel, Karawang, Jawa Barat 41361, Indonesia
Telp : +62-21 8911 5160, +62-267 861 0318 / 319 Fax : +62-267 8610290

**Declaration of Conformity (DoC)**

No. 30-DOC-BL-R-BIH-16-01

We,

Company name : PT. NIPRO INDONESIA JAYA
Postal address : Kawasan Industri Surya Cipta
Jalan Surya Utama Kav I-22B, 23, 24
Desa Kutamekar Kec. Ciampel
Karawang Timur 41361 Jawa Barat
Telephone number : +62(21)89115160; Fax : +62(267)8610290

declare that the DoC is issued under our sole responsibility and belongs to the following product:

Apparatus model/Product : Blood Tubing Set

EU Medical Device Class : IIa

No	Product Name	Type/Model	Packaging
1	BLOOD TUBING SET	A372R-V858R-BID	Plastic Bag
2	BLOOD TUBING SET	A363R-V849R-BID	Plastic Bag
3	BLOOD TUBING SET	A364R-V850R-BID	Plastic Bag
4	BLOOD TUBING SET	A365R-V851R-BID	Plastic Bag
5	BLOOD TUBING SET	A366R-V852R-BID	Plastic Bag
6	BLOOD TUBING SET	A164R-V732R-BID	Plastic Bag
7	BLOOD TUBING SET	A252R-V777R-BID	Plastic Bag
8	BLOOD TUBING SET	A295R-V806R-BID	Plastic Bag
9	BLOOD TUBING SET	A183R-V751R-BID	Plastic Bag
10	BLOOD TUBING SET	A188R-V756R-BID	Plastic Bag
11	BLOOD TUBING SET	A195R-V763R-BID	Plastic Bag
12	BLOOD TUBING SET	A280R-V791R-BID	Plastic Bag
13	BLOOD TUBING SET	A287R-V798R-BID	Plastic Bag
14	BLOOD TUBING SET	A289R-V800R-BID	Plastic Bag
15	BLOOD TUBING SET	A291R-V802R-BID	Plastic Bag
16	BLOOD TUBING SET	A316R-V814R-BID	Plastic Bag
17	BLOOD TUBING SET	A134R-V721R-BID	Plastic Bag
18	BLOOD TUBING SET	A176R-V684R-BID	Plastic Bag
19	BLOOD TUBING SET	A186R-V754R-BID	Plastic Bag
20	BLOOD TUBING SET	A179R-V747R-BID	Plastic Bag
21	BLOOD TUBING SET	A329R-V827R-BID	Plastic Bag
22	BLOOD TUBING SET	A427R-V909R-BID	Plastic Bag
23	BLOOD TUBING SET	A165R-V733R-BID	Plastic Bag
24	BLOOD TUBING SET	A290R-V801R-BID	Plastic Bag
25	BLOOD TUBING SET	A320R-V818R-BID	Plastic Bag
26	BLOOD TUBING SET	B0005R-BID	Plastic Bag



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The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

MDD 93/42/EEC
EN ISO 13485: 2016
EN ISO 14971: 2012

The following harmonised standards and technical specifications have been applied :

EN ISO 8638: 2014	EN ISO 14644-4: 2001
EN 62366-2: 2008	EN ISO 11607-1: 2009
MEDDEV 2.7.1 rev.4	EN ISO 11607-2: 2006
MEDDEV 2.12-2 rev.2	EN ISO 15223-1: 2016
EN ISO 10993-1: 2009/AC:2010	EN 1041: 2008+A1: 2013
EN ISO 10993-4: 2017	BS EN 15986: 2011
EN ISO 10993-5: 2009	EN 556-1: 2001
EN ISO 10993-10: 2013	EN ISO 11137-1: 2015
EN ISO 10993-11: 2009	EN ISO 11137-2: 2015
ISO 594-1: 1986	EN ISO 11137-3: 2017
ISO 594-2: 1998	ISO/TS 13004: 2013
EN ISO 14644-1: 2015	

EC-Representative : NIPRO MEDICAL EUROPE
Blokhuisstraat 42, 2800
Mechelen, Belgium

Notified body :
TUV NORD CERT GmbH
EC Certificate No. 44 232 127636 valid till 2024-03-07

notified body number: 0044

Signed for and on behalf of:

Karawang
Place of issue

2019-05-14
Date of issue

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Dwi Setiyono/ QA & RA Manager
Name, function, signature