

## DECLARATION OF CONFORMITY

Manufacturer's name NIPRO CORPORATION

Manufacturer's address 3-26, Senriokashinmachi, Settsu Osaka 566-8510,  
JAPAN

European Representative's name NIPRO MEDICAL EUROPE

European Representative's address Blokhuisstraat 42, 2800 Mechelen, BELGIUM

Name of device(s) (Classification and Rule) Blood Collecting Needles (IIa, Rule 6), Luer Adapter (IIa, Rule 6), Dental Needle (IIa, Rule 6)

Description of Device(s) See attachments

Applicable transitional provision pathway under the Regulation (EU) 2023/607 TÜV SÜD Product Service GmbH Confirmation Letter CL 043398 0320 Rev. 01

We hereby ensure and declare that the device(s) concerned meet(s) the provisions of the MDD 93/42/EEC and Article 120 (3) of MDR.

This declaration is supported by:

- EC Certificate full quality assurance system (Annex II excluding 4) issued by TÜV SÜD Product Service GmbH (ID No.0123), Ridlerstr. 65, D-80339 München, Germany.

EC Certificate No. No. G1 043398 0276 Rev. 01

First issue date: 31 October 2019

Expiry date of the Directive EC Certificate: 26 May 2024

End date of extended validity/transition period: 31 December 2028

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

Place Osaka, Japan

  
YOSHIDA Toyoshi  
Director  
Quality Assurance & Regulatory Compliance  
Headquarters

Date 10 October 2025

**Declaration of conformity version history**

Version	Issue date	Expiry date
0	31 March 2021	9 October 2025
1	10 October 2025	

Attached: Attachment 1-3

Attachment 1

Description of Blood Collecting Needles (IIa)

<b>Intended purpose</b>	Blood collection needles are intended to be used in combination with a holder and vacuum blood collection tubes for collecting blood sample for diagnosis and analysis.
<b>Harmonized standards and Common Specifications used for the device conformity assessment:</b>	EN ISO 11135:2014 EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 11737-1:2018

Product series name	REF No.
MULTIPLE DRAWING NEEDLE (Blood Collecting Needles)	NM-2025-EJ NM-2038-EJ NM-2125-EJ NM-2138-EJ NM-2225-EJ NM-2238-EJ NM-1825-EJ NM-1838-EJ
Vacumed MULTIPLE DRAWING NEEDLE (Blood Collecting Needles)	45201 45202 45203 45204 45205 45206 90201 90205 90211 90215 90221 90225

## Attachment 2

Description of Luer Adapter (IIa)**Intended purpose**

The luer adapter is intended to be used in combination with a device for blood collection (e.g., general needles, PSV, etc.), a holder, and a vacuum blood collection tube to collect a blood sample for diagnosis and analysis.

**Harmonized standards and Common Specifications used for the device conformity assessment:**

EN ISO 11135:2014  
EN ISO 13485:2016  
EN ISO 14971:2019  
EN ISO 11737-1:2018

Product series name	REF No.
Luer Adapter	LM-20-EJ
Vacumed LUER ADAPTER	45100

Attachment 3

Description of Dental Needle (IIa)

**Intended purpose**

A dental needle is a device for injecting an anesthetic, and it used for conduction anesthesia in dental treatment.

**Harmonized standards and Common Specifications used for the device conformity assessment:**

- EN ISO 11135:2014
- EN ISO 13485:2016
- EN ISO 14971:2019
- EN ISO 11737-1:2018
- EN ISO 11607-1:2020

Product series name	REF No.
Dental Needle	DN-2721-A EJ DN-2721-E EJ DN-2730-A EJ DN-2730-E EJ DN-2735-A EJ DN-2735-E EJ DN-2741-E EJ DN-3012-E EJ DN-3016-A EJ DN-3016-E EJ DN-3021-A EJ DN-3021-E EJ DN-3025-E EJ