

## DECLARATION OF CONFORMITY

Manufacturer's name Nipro Corporation

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

European Representative's name NIPRO MEDICAL EUROPE

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

Name of device(s) (Classification) PSV Sets(IIa)

Description of Device(s) See attachment

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



NAGASAWA Yoshiaki (Signature)  
General Manager  
Medical Regulatory Affairs Department,  
Quality Assurance & Regulatory  
Compliance Headquarters  
(Position)

Date 24 May 2022

Attached: Attachment

*Description of PSV Sets (IIa)*

Reference No.	Model
4056310N	19Gx3/4" (1,1x19 mm); L: 30 cm; Luer Lock
4056337N	21Gx3/4" (0,8x19 mm); L : 30 cm; Luer Lock
4056345N	22Gx3/4" (0,7x19 mm); L : 30 cm; Luer Lock
4056353N	23Gx3/4" (0,65x19 mm); L : 30 cm; Luer Lock
4056361N	24Gx3/4" (0,55x19 mm); L : 30 cm; Luer Lock
4056370N	25Gx3/4" (0,5x19 mm); L : 30 cm; Luer Lock
4056388N	27Gx5/8" (0,4x16 mm); L: 30 cm; Luer Lock