

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

Date 2 May 2022

Attached: Attachment

Safe Touch PSV for B Braun customer

Ref No.	Model
4056505N	ST. PSV Set 19Gx3/4" Hard with EL luer cap 30cm
4056506N	ST. PSV Set 21Gx3/4" Hard with EL luer cap 19cm
4056504N	ST. PSV Set 21Gx3/4" Hard with EL luer cap 30cm
4056503N	ST. PSV Set 23Gx3/4" Hard with EL luer cap 30cm
4056502N	ST. PSV Set 25Gx3/4" Hard with EL luer cap 30cm