EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson Infusion Therapy AB Florettgatan 29C, PO Box 631 SE-251 06 Helsingborg, Sweden
Manufacturing Site(s):	Becton Dickinson Medical (S) Pte Ltd. 30 Tuas Avenue 2, Singapore 639461 Singapore
Products:	**BD Neoflon™ Pro I.V. Cannula** ▪ 391379 26GA BD Neoflon Pro ▪ 391380 24GA BD Neoflon Pro ▪ 391389 26GA BD Neoflon Pro - INDIA ▪ 391390 24GA BD Neoflon Pro - INDIA
Classification:	Class IIa, Annex IX, Rule 7
Conformity Assessment Route:	Annex II, section 3.2
GMDN:	▪ GMDN Code: 64574 ▪ GMDN Term: Peripheral intravenous cannula

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer.

Harmonised Standards:	EN ISO 13485:2016 EN ISO 14971:2012 EN 20594-1:1993 EN ISO 10555-1:2014 EN ISO 10555-5:2013 EN ISO 10993-1:2009 EN ISO 10993-7:2008 EN ISO 11607-1:2009 EN ISO 11607-2:2006 EN 556-1:2001 EN ISO 11137-1:2006 EN ISO 11137-2:2015 EN ISO 11737-1:2006 EN ISO 11737-2:2009 EN 1041:2008

TITLE: Declaration of Conformity for BD Neoflon ™ Pro Products

	EN ISO 11135-1:2014
Non-Harmonised Standards:	ISO 594-2:1998 ISO 14644-1:1999 ISO 9626 ISO 10555-1:2013 ISO 10555-5:2013 ISO 80369-7:2016
Notified Body:	BSI Group, The Netherlands B.V. Say Buidling, John M. Keynesplein 9 Amsterdam 1066 EP Netherlands Notified Body ID Number: 2797
CE Certificate Number:	CE 597884
Date of issuance of original CE certificate:	11 January 1996

Date: 4th May 2020

Heather HAGVIK

Senior Regulatory Specialist

Becton Dickinson Infusion Therapy, AB

Becton Dickinson Infusion Therapy AB
Florettgatan 29 C
PO Box 631
SE-251 06 Helsingborg
Sweden

TITLE: Declaration of Conformity for BD Neoflon ™ Pro Products

REVISION HISTORY

Current Version Prepared By: Heather Hagvik

REV.	Revision Description	Releasing ECO (if applicable)
A	Initial Release, New DoC into SAP. Updated Notified body number.	NA
B	Added signature	N/A
C	Added new GMDN code	N/A

Do not include revision history page in page numbering.