



Manufacturer's Declaration of Certificate Validity:

with respect to the validity of certificates issued under Council Directive 93/42/EEC on medical devices that have been extended as a result of the REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Manufacturer name	Becton Dickinson Infusion Therapy, AB
Manufacturer address	Florettgatan 29C, PO Box 631 SE-251 06 Helsingborg, Sweden
EUDAMED SRN (if available)	SE-MF-000014597

Authorised Representative name (if applicable)	Not Applicable
Authorised Representative address	Not Applicable
EUDAMED SRN (if available)	Not Applicable
BSI Group The Netherlands B.V. #2797 - For verification contact BSI: Certificate.Verification@bsigroup.com	MDR application signed. December 19, 2019

This declaration confirms that the devices listed in the attached schedule meet following conditions for extension of their certificates issued under Council Directive 93/42/EEC (MDD) as stated in the regulation 2023/607:

- The certificate(s) covering the listed devices was valid on the 26 May 2021.
- The devices continue to comply with Directive 93/42/EEC (MDD)
- There are no significant changes in the design and intended purpose since 26 May 2021.
- The device(s) do not present unacceptable risks to health or safety of patients, users or other persons, or to other aspects of the protection of public health.
- A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) has been put in place by the manufacturer.
- A formal application to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made for the device(s) listed and a signed written agreement is in place in accordance with Section 4.3, second subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR) before the expiry date of the listed certificate.
- Post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.

Signed for and on behalf of the manufacturer:

Signature: 

Date: October 18, 2023

Print name: Katarina Rietz

Title/position: QA/RA Manager

Manufacturer name: Becton Dickinson
Infusion Therapy, AB

Schedule of devices

Model Number/Catalogue number	Device Name	Certificate numberⁱ	Expiry date on the certificateⁱⁱ	Extended expiry dateⁱⁱⁱ
394501	BD Connecta™ stopcock with BD Q-Syte™ luer access split septum - 360° White tap with Q-Syte	CE 597884	08-Jan-24	31-Dec-28*
394502	BD Connecta™ stopcock with BD Q-Syte™ luer access split septum - 360°Red tap with Q-Syte	CE 597884	08-Jan-24	31-Dec-28*
394600	BD Connecta™ stopcock without extension tube - white	CE 597884	08-Jan-24	31-Dec-28*
394601	BD Connecta™ stopcock without extension tube - White with color pegs	CE 597884	08-Jan-24	31-Dec-28*
394602	BD Connecta™ stopcock without extension tube - blue	CE 597884	08-Jan-24	31-Dec-28*
394605	BD Connecta™ stopcock without extension tube - red	CE 597884	08-Jan-24	31-Dec-28*
394900	BD Connecta™ stopcock without extension tube - White blend	CE 597884	08-Jan-24	31-Dec-28*
394906	BD Connecta™ stopcock without extension tube - White not ISO blend	CE 597884	08-Jan-24	31-Dec-28*
394910	BD Connecta™ Stopcock with OFF directed tap without extension tube - 360 white	CE 597884	08-Jan-24	31-Dec-28*
394911	BD Connecta™ Stopcock with OFF directed tap without extension tube - 360 blue	CE 597884	08-Jan-24	31-Dec-28*
394926	BD Connecta™ Stopcock with extension tube - 25 cm	CE 597884	08-Jan-24	31-Dec-28*
394936	BD Connecta™ Stopcock with extension tube and injection valve - 25 cm ventil	CE 597884	08-Jan-24	31-Dec-28*
394945	BD Connecta™ Stopcock with extension tube and injection valve - 7 cm ventil	CE 597884	08-Jan-24	31-Dec-28*
394951	BD Connecta™ Stopcock with extension tube - 50 cm	CE 597884	08-Jan-24	31-Dec-28*

394961	BD Connecta™ Stopcock with extension tube - 100 cm	CE 597884	08-Jan-24	31-Dec-28*
394971	BD Connecta™ Stopcock with extension tube and injection valve - 100 cm ventil	CE 597884	08-Jan-24	31-Dec-28*
394982	BD Connecta™ Stopcock with low volume extension tube (for pediatric use) - 15 cm	CE 597884	08-Jan-24	31-Dec-28*
394983	BD Connecta™ Stopcock with low volume extension tube (for pediatric use) - 30 cm	CE 597884	08-Jan-24	31-Dec-28*
394995	BD Connecta™ Stopcock with extension tube - white 10 cm	CE 597884	08-Jan-24	31-Dec-28*
394997	BD Connecta™ Stopcock with extension tube - Blue 10 cm	CE 597884	08-Jan-24	31-Dec-28*
395000	BD Connecta™ stopcock without extension tube - White and green	CE 597884	08-Jan-24	31-Dec-28*
395061	BD Connecta™ Stopcock with extension tube - 100cm	CE 597884	08-Jan-24	31-Dec-28*
395095	BD Connecta™ Stopcock with extension tube - 10cm	CE 597884	08-Jan-24	31-Dec-28*
391379	NEOFLON PRO 26GA 0.6MM OD 19MM L	CE 597884	08-Jan-24	31-Dec-28*
391380	NEOFLON PRO 24GA 0.7MM OD 19MM L	CE 597884	08-Jan-24	31-Dec-28*
391389	NEOFLON PRO 26GA 0.6MM OD 19MM L INDIA	CE 597884	08-Jan-24	31-Dec-28*
391390	NEOFLON PRO 24GA 0.7MM OD 19MM L INDIA	CE 597884	08-Jan-24	31-Dec-28*
391451	VENFLON 2 BL 22GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391452	VENFLON 2 PNK 20GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391453	VENFLON 2 GN 18GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391454	VENFLON 2 WH 17GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391455	VENFLON 2 GR 16GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391456	VENFLON 2 BR 14GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391457	VENFLON 2 GN 18GA IV CANNULA 32MM	CE 597884	08-Jan-24	31-Dec-28*
391491	VENFLON 2 - 22G	CE 597884	08-Jan-24	31-Dec-28*
391492	VENFLON 2 - 20G	CE 597884	08-Jan-24	31-Dec-28*
391493	VENFLON 2 - 18G	CE 597884	08-Jan-24	31-Dec-28*
391495	VENFLON II-16G	CE 597884	08-Jan-24	31-Dec-28*

W

391496	VENFLON II-14G	CE 597884	08-Jan-24	31-Dec-28*
391591	VENFLON I 22GA 0.8 MM X 25MM	CE 597884	08-Jan-24	31-Dec-28*
391592	VENFLON I 20GA 1.0 MM X 32MM	CE 597884	08-Jan-24	31-Dec-28*
391593	VENFLON I 18GA 1.2 MM X 45MM	CE 597884	08-Jan-24	31-Dec-28*
391595	VENFLON I 16GA 1.7 MM X 45MM	CE 597884	08-Jan-24	31-Dec-28*
391596	VENFLON I 14GA 2.0 MM X 45MM	CE 597884	08-Jan-24	31-Dec-28*
391891	VENFLON I 22GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391892	VENFLON I 20GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391893	VENFLON I 18GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391895	VENFLON I 16GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
391896	VENFLON I 14GA IV CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393222	VENFLON PRO SAFETY 22GA 0.9MM OD 25MM L	CE 597884	08-Jan-24	31-Dec-28*
393224	VENFLON PRO SAFETY 20GA 1.1MM OD 32MM L	CE 597884	08-Jan-24	31-Dec-28*
393226	VENFLON PRO SAFETY 18GA 1.3MM OD 32MM L	CE 597884	08-Jan-24	31-Dec-28*
393227	VENFLON PRO SAFETY 18GA 1.3MM OD 45MM L	CE 597884	08-Jan-24	31-Dec-28*
393228	VENFLON PRO SAFETY 17GA 1.5MM OD 45MM L	CE 597884	08-Jan-24	31-Dec-28*
393229	VENFLON PRO SAFETY 16GA 1.8MM OD 45MM L	CE 597884	08-Jan-24	31-Dec-28*
393230	VENFLON PRO SAFETY 14GA 2.0MM OD 45MM L	CE 597884	08-Jan-24	31-Dec-28*
393242	VENFLON PRO SAFETY 22GA INDIA	CE 597884	08-Jan-24	31-Dec-28*
393244	VENFLON PRO SAFETY 20GA INDIA	CE 597884	08-Jan-24	31-Dec-28*
393246	VENFLON PRO SAFETY 18GA 32MM L INDIA	CE 597884	08-Jan-24	31-Dec-28*
393247	VENFLON PRO SAFETY 18GA 45MM L INDIA	CE 597884	08-Jan-24	31-Dec-28*
393248	VENFLON PRO SAFETY 17GA INDIA	CE 597884	08-Jan-24	31-Dec-28*
393249	VENFLON PRO SAFETY 16GA INDIA	CE 597884	08-Jan-24	31-Dec-28*
393250	VENFLON PRO SAFETY 14GA INDIA	CE 597884	08-Jan-24	31-Dec-28*
393280	VENFLON PRO SAFETY 22GA INSTAFLASH	CE 597884	08-Jan-24	31-Dec-28*

393281	VENFLON PRO SAFETY 20GA INSTAFLASH	CE 597884	08-Jan-24	31-Dec-28*
393282	VENFLON PRO SAFETY 18GA INSTAFLASH	CE 597884	08-Jan-24	31-Dec-28*
393283	VENFLON PRO SAFETY 18GA INSTAFLASH	CE 597884	08-Jan-24	31-Dec-28*
393284	VENFLON PRO SAFETY 22GA I.V CANNULA WITH INSTAFLASH - INDIA	CE 597884	08-Jan-24	31-Dec-28*
393285	VENFLON PRO SAFETY 20GA I.V CANNULA WITH INSTAFLASH - INDIA	CE 597884	08-Jan-24	31-Dec-28*
393286	VENFLON PRO SAFETY 18GA I.V CANNULA WITH INSTAFLASH - INDIA	CE 597884	08-Jan-24	31-Dec-28*
393287	VENFLON PRO SAFETY 18GA I.V CANNULA WITH INSTAFLASH - INDIA	CE 597884	08-Jan-24	31-Dec-28*
393202	VENFLON PRO 22GA I.V CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393204	VENFLON PRO 20GA I.V CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393206	VENFLON PRO 18GA I.V CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393207	VENFLON PRO 18GA I.V CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393208	VENFLON PRO 17GA I.V CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393209	VENFLON PRO 16GA I.V CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393210	VENFLON PRO 14GA I.V CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393232	VENFLON PRO 22GA I.V CANNULA- INDIA	CE 597884	08-Jan-24	31-Dec-28*
393234	VENFLON PRO 20GA I.V CANNULA- INDIA	CE 597884	08-Jan-24	31-Dec-28*
393236	VENFLON PRO 18GA I.V CANNULA- INDIA	CE 597884	08-Jan-24	31-Dec-28*
393237	VENFLON PRO 18GA I.V CANNULA- INDIA	CE 597884	08-Jan-24	31-Dec-28*
393238	VENFLON PRO 17GA I.V CANNULA- INDIA	CE 597884	08-Jan-24	31-Dec-28*
393239	VENFLON PRO 16GA I.V CANNULA- INDIA	CE 597884	08-Jan-24	31-Dec-28*
393240	VENFLON PRO 14GA I.V CANNULA- INDIA	CE 597884	08-Jan-24	31-Dec-28*
393252	VENFLON PRO 22GA I.V. CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393254	VENFLON PRO 20GA I.V. CANNULA	CE 597884	08-Jan-24	31-Dec-28*
393256	VENFLON PRO 18GA I.V. CANNULA	CE 597884	08-Jan-24	31-Dec-28*

W

i Number of certificate issued under Directive 93/42/EEC (MDD) or 90/385/EEC (AIMDD)

ii The expiry date on the certificate issued under Directive 93/42/EEC (MDD) or 90/385/EEC (AIMDD)

iii Extended expiry date according to Article 120 3b and 3c, Regulation (EU) 2017/745 (MDR)

* The use the Article 97 derogation process is recommended when there is a change of the legal manufacturer



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

September 21, 2023

Notified Body Confirmation Letter
Reference: EU2023-607/693660

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Becton Dickinson Infusion Therapy AB
Florettgatan 29C
PO Box 631
SE-251 06 Helsingborg
Sweden
SRN Number (if available): SE-MF-000014597

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,



Luis Martinez
BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BD Venflon Pro™ I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Venflon™ I I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Venflon™ I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Venflon™ Pro Safety I.V. Cannula with Instaflash™ Needle Technology	Class IIa	N/A	CE 597884; NB 2797
BD Venflon Pro™ Safety I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Neoflon™ Pro I.V. Cannula	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with OFF directed tap without Extension Tube	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock without Extension Tube	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with Extension Tube	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with Low volume Extension Tube	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with Extension Tube and Injection valve	Class IIa	N/A	CE 597884; NB 2797
BD Connecta™ Stopcock with BD Q-Syte™ Luer Access Split-Septum	Class IIa	N/A	CE 597884; NB 2797
BD Plug Luer-Lok™	Class IIa	N/A	CE 597884; NB 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/09/21	Initial issue

TITLE: Declaration of Conformity for BD Connecta™ Stopcock Products
Page 1 of 3

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 Infusion Therapy Systems Inc. S.A. de C.V., Periferico Luis Donaldo Colosio#579 Nogales, Sonora C.P. 84048 Mexico	
Product Family:	Product Trade name:	Description:
BD Connecta™ Stopcocks	BD Connecta™	Stopcock with OFF directed tap without extension tube <ul style="list-style-type: none"> ▪ 394908 BD Connecta™ ▪ 394910 BD Connecta™ ▪ 394911 BD Connecta™ ▪ 394912 BD Connecta™
		Stopcock without extension tube <ul style="list-style-type: none"> ▪ 394600 BD Connecta™ ▪ 394601 BD Connecta™ ▪ 394602 BD Connecta™ ▪ 394605 BD Connecta™ ▪ 394900 BD Connecta™ ▪ 394901 BD Connecta™ ▪ 394902 BD Connecta™ ▪ 394906 BD Connecta™ ▪ 395000 BD Connecta™ (INDIA)
		Stopcock with extension tube <ul style="list-style-type: none"> ▪ 394995 BD Connecta™ 10 cm ▪ 394997 BD Connecta™ 10 cm ▪ 394926 BD Connecta™ 25 cm ▪ 394951 BD Connecta™ 50 cm ▪ 394961 BD Connecta™ 100 cm ▪ 395095 BD Connecta™ 10 cm (INDIA) ▪ 395061 BD Connecta™ 100 cm (INDIA)
		Stopcock with low volume extension tube <ul style="list-style-type: none"> ▪ 394982 BD Connecta™ 15 cm ▪ 394983 BD Connecta™ 30 cm

TITLE: Declaration of Conformity for BD Connecta™ Stopcock Products
Page 2 of 3

		<p>Stopcock with extension tube and injection valve</p> <ul style="list-style-type: none"> ▪ 394945 BD Connecta™ 7 cm ▪ 394936 BD Connecta™ 25 cm ▪ 394971 BD Connecta™ 100 cm
Classification:	Class IIa, Annex IX, Rule 2	
Conformity Assessment Route:	Annex II, section 3.2	
GMDN:	<ul style="list-style-type: none"> ▪ GMDN Code: 32172 ▪ GMDN Term: Intravenous line stopcock 	

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:	<p>EN ISO 13485:2016 EN ISO 14971:2012 EN 20594-1:1993 EN ISO 10993-1:2018 EN ISO 11607-1:2017 EN ISO 11607-2:2017 EN 556-1:2001 EN ISO 11137-1:2015 EN ISO 11137-2:2015 EN ISO 11737-1:2018 EN ISO 11737-2:2009 EN 1041:2008 EN 62366:2015</p>
Non-Harmonised Standards:	<p>ISO 594-2:1998 ISO 15223-1:2012 ISO 14644-1:2015</p>
Notified Body:	<p>BSI Group, The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP, Amsterdam Netherlands Notified Body ID Number: 2797</p>
CE Certificate Number:	CE 597884



Document Number: TF002HEL_DOC

Document Type: ZRF

Version: E

TITLE: Declaration of Conformity for BD Connecta™ Stopcock Products
Page 3 of 3

Date of issuance of original CE certificate:	11 January 1996
---	-----------------

Signed: September 11, 2023

Katarina Rietz
QA/ RA Manager
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 Connecta™ Stopcock Products

Page 1 of 1

REVISION HISTORY

Current Version Prepared By: Heather Hagvik

REV.	Revision Description	Releasing ECO (if applicable)
A	Initial Release, New DoC into SAP. Added in new Notified body number.	NA
B	Added signature	NA
C	Updated DOC with Product trade name and product descriptions, updated newer standards in table	NA
D	Updated GMDN term	NA
E	SKU 394905 obsolete per MEMO HBG_037 Annual review of DoC and updated Signee to Katarina Rietz	NA

[Do not include revision history page in page numbering.](#)