



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*

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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*

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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

