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URGENT: FIELD SAFETY NOTICE – MDS-21-4072

Infusion Sets for

Alaris™ Pumps (GP, VP, CC, GW/GW800, SE, IVAC 590 series) (Appendix 1)

Gravity Infusion sets & connectors (Appendix 2)

Type of Action: Product Removal

<<Date>>

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove all lots of distributed:

- **Infusion Sets for Alaris™ Pumps (GP, VP, CC, GW/GW800 and SE, IVAC 590 series)** and
- **Gravity Infusion sets and connectors**.

See Appendices 1 and 2 for full lists of all impacted product catalogue numbers (REFs). Representative images of the devices are provided in Table 1 and 2 below.

Description of the Problem

BD has been notified by a 3rd party sterilization services provider that it intentionally falsified sterilization process records related to the processing of BD products.

BD immediately conducted an investigation and has determined that BD is unable to guarantee the sterility of the devices listed in the attached appendices. Therefore, we are removing the devices from the market.

The scope of this product removal includes unexpired lots of the distributed SKUs listed in the appendices. BD has an on-line tool to support the identification of impacted lot numbers <<insert weblink>>.

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Table 1: Representative examples of Infusion Sets for Alaris™ Pumps (GP, VP, CC, GW/GW800 and SE), IVAC 590 series

	Product	Purpose	Alternative
	Large volume Infusion Pump Sets	Accurate IV infusion and transfusion delivery in general wards OR and ICU	No alternative sets – see Clinical advice below
	Syringe Pump Sets with In-Line Pressure Monitoring	Accurate IV infusion and transfusion delivery in general wards, OR and ICU	No alternative sets – see Clinical advice below

Table 2: Representative examples of Gravity IV sets & connectors

	Product	Purpose	Alternative
	Primary and secondary administration sets	IV fluids and drugs administration	Other non-dedicated IV sets from BD or competitor portfolio. Contact local representative
	Transfusion sets	Blood transfusions	Other transfusion sets from BD or competitor portfolio. Contact local representative
	Multi-way oncology sets	Oncology drug infusion delivery	Other oncology sets from BD or competitor portfolio. Contact local representative
	SmartSite™ Needle-Free Connector	Needleless connector to enable catheter access to infusion	Other connector technology from BD or competitor portfolio. Contact local representative
	Vial and bag access devices	Needleless bag and vial access, including hazardous drug protection	Contact local representative

Clinical Impact:

The use of non-sterile devices in the clinical setting could lead to an increased risk of infection which may cause serious harm or life-threatening conditions.

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BD has not identified any reports of adverse events or serious patient harm to date that could be associated to this field safety corrective action. No specific patient follow-up activities are required if the product has already been used.

Advice for Clinical Users:

1. Cease use of all impacted lot numbers in your possession.

2. Until BD can resume shipments, BD recommends:

   a. Contact your local BD representative to discuss possible product alternatives.

   b. Where product alternatives are not available, consider general measures to guarantee infusion continuity such as:

   For Alaris™ CC Plus users:
   i) Check with local representative and Technical support the possibility to temporarily convert you pump into "Semi-dedicated" mode (allows pump operation only in ml/h and without In-line pressure monitoring capability) using standard extension sets as an alternative.
   ii) Should filtration be a requirement, add-on filters (0.22 / 1.2µm filters) can be used.
   iii) Due to limited supply of extension sets with pressure disc, In Line Pressure Measurements may not be possible. Hence, we recommend using a pressure disc on ONE pump that is closest to the patient so it can monitor the in-line pressure for all pumps in the system (i.e. multi infusion set up).

   For Alaris™ GP Plus & Alaris™ SE & Alaris ™ IVAC 590 series users:
   i) Consider use of syringe pumps for high-alert medications that require continuous infusions (including weighed-based drugs) or gravity alternatives if clinically acceptable.
   ii) Use any alternative pumps available.
   iii) Consider use of gravity infusions for large volume infusates that do not require high-accuracy or weighed-based infusion.
   iv) When transitioning parenteral nutrition or chemotherapy or other infusions that require infusion sets with filters (0.2 or 1.2 µm), consider use of add-on inline filters during gravity-based infusions (with or without flow rate regulators).
   v) Consider use of tubing with integrated dial-calibrated IV flow rate regulators (e.g., RATE FLOW regulator, DIAL-A-FLOW) can be used to regulate the flow rate instead of the roller clamp.

   For Alaris™ VP Plus and GW/GW800 users:
   i) As pump set replacement alternatives are not possible, gravity infusion may be the only option or use any alternative pumps available.
   ii) Consider use of syringe pumps for high-alert medications that require continuous infusions (including weight-based drugs). The set recommendations below might not be identical to the sets you have been using but will match the essential clinical requirements.
   iii) Consider use of gravity infusions for large volume infusates that do not require high-accuracy or weight-based infusion.
   iv) When transitioning parenteral nutrition or chemotherapy or other infusions that require infusion sets with filters (0.2 or 1.2 µm), consider use of add-on inline filters during gravity-based infusions (with or without flow rate regulators).

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    v)   Consider use of tubing with integrated dial-calibrated IV flow rate regulators (e.g., RATE FLOW regulator, DIAL-A-FLOW) can be used to regulate the flow rate instead of the roller clamp.

c.   Consider alternative arrangements for your infusion therapy needs either in line with national or local guidance or the guidance from **ISMP (Institute for Safe Medication Practices**, an ECRI affiliate), for alternative infusion therapy arrangements in situations of supply interruptions for IV disposables:

    i.   **IV to oral conversion**. Organizations should switch patients from IV to oral therapies as soon as possible. This should be considered for all appropriate patients who can swallow and meet other facility-defined criteria (e.g., no fever), including patients in the emergency department (ED) and long-term care facilities associated with the health system.

    ii.   **Use IV push instead of infusions.** Administering medications via IV push instead of as a secondary infusion should also be considered when appropriate. Hospital-specific IV push guidelines, along with the ISMP Safe Practice Guidelines for Adult IV Push Medications, should be consulted before considering this alternative.

    iii.   **Potential role for gravity infusions.**   Examples may include IV hydration, some IV antibiotics, medications that are not high-alert, and others that might be appropriate for gravity infusion upon assessment during the ordering and dispensing process. To gauge the rate of flow in mL/hour for gravity infusions, it is necessary to know how many drops per mL the administration set delivers (e.g., 10, 15, 20, 60 drops per mL). The number of drops delivered is controlled by the roller clamp (gravity flow control clamp).

    iv.   **Other alternatives.** Other alternative types of infusion devices should be considered during infusion pump shortages, such as volumetric burette tubing, elastomeric devices, and other non-electronic rate controllers.

Source: ISMP (April 2020). Available at https://ismp.org/resources/planning-anticipated-shortage-smart-infusion-pumps-and-dedicated-administration-sets

<u>Customer Next Steps:</u>

1. Circulate this Field Safety Notice to all those in your organisation, that need to be made aware.
   - If you have further distributed the product, please identify those facilities, and forward this notification to them immediately.

2. Use the BD online tool <<insert weblink>> to identify lot numbers in your inventory which are impacted by this product recall.
   - *NOTE: If you are unable to access the online tool, please contact your local BD representative.*

3. Quarantine and destroy any units of the impacted lots and complete the customer response form on Page x and return to <<insert contact details here>> for replacement product **as soon as possible or no later than 16th April 2021.**

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Corrective Actions by BD

BD is working to qualify an alternate sterilization facility for these devices.

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

<<Insert Signature here>>	<<Insert Signature here>>	<<Insert Signature here>>
Prof. Dr. Klaus Hoerauf, Vice President Medical Affairs, EMEA Region BD Switzerland Sàrl	Idal Beer, MD Vice President Medical Affairs, Medication Management Solutions	Frédérique Pedretti-Abel Vice President EMEA Quality BD Switzerland Sàrl

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Customer Response Form – MDS-21-4072

Infusion Sets for Alaris™ Pumps (GP, VP, CC, GW/GW800 and SE, IVAC 590 series)

& Gravity Infusion sets & connectors

Please read in conjunction with Field Safety Notice MDS-21-4072 and return completed and signed form as soon as possible or **no later than the 16ᵗʰ April 2021** to *<<insert fax/email address here>>*.

- **I confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

Tick the appropriate box below

☐ We do not have any of the impacted devices as listed in Appendix 1 in our possession.

OR

☐ We have the units of the impacted devices as listed in Appendix 1 in our possession and I confirm that the following units have been destroyed/returned in return for replacement as indicated below. (*Please note there may be delays in the replacement product subject to product availability).*

SKU	Lot Number	Quantity Destroyed	SKU	Lot Number	Quantity Destroyed

Account/Organisation Name:	
Department *(if applicable)***:**	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Signature:	**Date:**

This form must be returned to BD before this action can be considered closed for your account.

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Appendix 1: Infusion Sets for Alaris™ Pumps (GP, VP, CC, GW/GW800 and SE, IVAC 590 series)

All products listed in Appendix 1, manufactured by BD Switzerland Sàrl, Terre Bonne Park – A4, Route de Crassier 17, Eysins, Switzerland unless otherwise indicated.

Product Catalogue (REFs)	Product Name
Infusion Sets for Alaris™ CC Syringe Pump	
G30402M	Alaris™ Products. Alaris™ CC Syringe Pump, Asena™ CC Syringe Pump, IVAC™ 701/711/770/P7000 Pumps. EXTENSION SET.
G30453V	Alaris™ Products. Alaris™ CC Syringe Pump, Asena™ CC Syringe Pump, IVAC™ P7000 Pumps. EXTENSION SET. LIGHT RESISTANT. LOW SORBING (PE/PVC)
G30653V	Alaris™ Products. Alaris™ CC Syringe Pump, Asena™ CC Syringe Pump, IVAC™ P7000 Pumps. EXTENSION SET. LIGHT RESISTANT.
Infusion Sets for Alaris™ GP Volumetric Pump	
60593	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 μm FILTER.
60643	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LIGHT RESISTANT. 15 μm FILTER.
60693	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 μm FILTER.
60793	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 μm FILTER.
60894	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 200 μm FILTER.
60895	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 200 μm FILTER.
60903	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 μm FILTER.
60980	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 2 SPIKE. 200 μm FILTER.
60093E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 μm FILTER.
60123E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 1.2 μm FILTER.
60173E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
60393E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. TRANSFUSION / BLOOD SET. 200 μm FILTER.
60693E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 μm FILTER.
60793E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 μm FILTER.
60950E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 μm FILTER.
60951E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 μm FILTER.
60952E	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 μm FILTER.
60953V	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING. 15 μm FILTER.
63200NYB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. NO FILTER.
63401EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
63402BE	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
63420EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
63423BE	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
63477EB	Alaris™ Products. Alaris™ GP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. TRANSFUSION/BLOOD SET. 2 SPIKE. 200 μm FILTER.
Infusion Sets for Alaris™ GW Volumetric Pump	

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273-001V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 15 µm FILTER.
273-002V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 15 µm FILTER.
273-003V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 15 µm FILTER.
273-007V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. TRANSFUSION/BLOOD SET. 200 µm FILTER.
273-008EV	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free Valve. Alaris™ GW 800 Volumetric Pump. TRANSFUSION/BLOOD SET. 200 µm FILTER.
273-009V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 1.2µm FILTER.
273-022V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. ANTI-SIPHON VALVE. 0.2µm FILTER.
273-043V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. LIGHT RESISTANT. ANTI-SIPHON VALVE. 15 µm FILTER.
273-053V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. LOW SORBING. ANTI-SIPHON VALVE. 15 µm FILTER.
273-080EV	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. LOW SORBING. ANTI-SIPHON VALVE. 15 µm FILTER.
273-103EV	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. BURETTE SET. ANTI-SIPHON VALVE. NO FILTER.
273-303EV	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. BURETTE SET. ANTI-SIPHON VALVE. NO FILTER.
273-304V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. 15 µm FILTER.
273-950EB	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
273-951EB	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
273-952EB	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. MULTI-INFUSION SET. ONCOLOGY. LOW SORBING (TPU/EVA). LIGHT RESISTANT. VENTED. 15 µm FILTER.
273-954EB	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. SmartSite™ Needle-free System. Alaris™ GW 800 Volumetric Pump. MULTI-INFUSION SET. ONCOLOGY. LOW SORBING (TPU/EVA). LIGHT RESISTANT. VENTED. 15 µm FILTER.
273-004V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. 15 µm FILTER.
273-005V	Alaris™ Products. Alaris™ GW Volumetric Pump. Asena™ GW Volumetric Pump. Alaris™ GW 800 Volumetric Pump. INFUSION SET. NO FILTER.
0000TG00074	GW Calibration tubing
Infusion Sets for Alaris™ VP Volumetric Pump	
70096	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW PRIMING VOLUME. 15 µm FILTER.
70593	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.
70641	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW PRIMING VOLUME. LIGHT RESISTANT. 15 µm FILTER.
70643	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LIGHT RESISTANT. 15 µm FILTER.
70895	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 200 µm FILTER.
70896	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. TRANSFUSION/BLOOD SET. 2 SPIKE. 200 µm FILTER.
70953	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING. 15 µm FILTER.
70033V	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. INFUSION SET. LOW SORBING. 0.2 µm FILTER.
70093E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
70103E	Burette Set. No Filter. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. BURETTE SET. NO FILTER.
70123E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. LIGHT RESISTANT. 1.2 µm FILTER.

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70125E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. UNVENTED. 1.2 µm FILTER.
70693E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
70793E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. NO FILTER.
70950E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
70951E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 µm FILTER.
70952E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 µm FILTER.
70954E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. VENTED. 15 µm FILTER.
70955E	Alaris™ Products. Alaris™ VP Volumetric Pump. Alaris™ Safety Clamp. SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. 2 SPIKE. VENTED. 15 µm FILTER.
Infusion Sets for Alaris™ SE Volumetric Pump	
71980B	Alaris™ SE Pump. Transfusion/Blood Set.200 µm Filter.
72001EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. 15 µm Filter.
72013EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. No Filter.
72024EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. 15 µm Filter.
72304B	Alaris™ SE Pump. Infusion Set. 15 µm Filter.
72504EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. 15 µm Filter.
72643EB	Alaris™ SE Pump. SmartSite™ Needle-free System. Infusion Set. Light Resistant. 15 µm Filter.
72953B	Alaris™ SE Pump. Infusion Set. Low Sorbing. 15 µm Filter.
MFX72950EB	Multi-infusion set. Oncology. Vented. 15 µm Filter.
MFX72951EB	Multi-infusion set. Oncology. Vented. 15 µm Filter.
MFX72952EB	Multi-infusion set. Oncology. Low Sorbing (TPU/EVA). Light Resistant. Vented. 15 µm Filter.
MFX72954EB	Multi-infusion set. Oncology. Low Sorbing (TPU/EVA). Light Resistant. Vented. 15 µm Filter.
Infusion Sets for Alaris™ IVAC™ 590 Pump Volumetric Pump	
G59073	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59123E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. SmartSite™ Needle-free System. INFUSION SET. 1.2 µm FILTER.
G59173E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. SmartSite™ needle-free system. INFUSION SET. NO FILTER.
G59293E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59593F	Alaris™ Products. Alaris™ GP Volumetric Pump. IVAC™ 590 Series Volumetric Pumps. Alaris™ Safety Clamp. INFUSION SET. 15 µm FILTER.
G59693FE	Alaris™ Products. Alaris™ GP Volumetric Pump. IVAC™ 590 Series Volumetric Pumps. Alaris™ Safety Clamp. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
G59793	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59793E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.
G59953V	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. LOW SORBING. 15 µm FILTER.
G59593	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59643	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. LIGHT RESISTANT. 15 µm FILTER.
G59693	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. INFUSION SET. 15 µm FILTER.
G59693E	Alaris™ Products. IVAC™ 590 Series Volumetric Pumps. SmartSite™ Needle-free System. INFUSION SET. 15 µm FILTER.

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Appendix 2: Gravity IV sets & connectors

All product listed in Appendix 2, manufactured by BD Switzerland Sàrl, Terre Bonne Park – A4, Route de Crassier 17, Eysins, Switzerland unless otherwise indicated

Product Catalogue (REFs)	Product Name
Needle-free connectors stand-alone	
2000E7D	SmartSite™ Needle-Free Valve
ARD Sets	
388000	BD Gravity IV Set with Anti-Run Dry (ARD) technology and Auto Prime. Infusion Set. Vented.
388002	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Infusion Set. Vented.
388004	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. Micro Infusion Set. Vented.
388006	BD Gravity IV set with Anti-Run Dry (ARD) Technology and AutoPrime. SmartSite™ Needle-free System. Micro Infusion Set. Vented.
388010	BD Gravity Burette Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. 150ml Micro Burette Set.
388013	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Infusion Set. Vented.
388015	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Flow Controller. Infusion Set. Vented.
388017	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Flow Controller. Infusion Set. Vented. 0.2µm Filter.
388018	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Flow Controller. Infusion Set. Vented. 1.2µm Filter.
388019	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Flow Controller. Infusion Set. Vented.
388020	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Infusion Set. Vented. 0.2µm Filter.
388021	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and Auto Prime. SmartSite™ Needle-free System. Infusion Set. Vented. 1.2µm Filter.
388050	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. Back Check Valve. Infusion Set. Vented. Back Check Valve.
388051	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. BACK CHECK VALVE – SMARTSITE™ NEEDLE-FREE SYSTEM.
388053	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. INFUSION SET. VENTED. Gravity flow only.
388125	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. INFUSION SET. VENTED. Gravity flow only.
388126	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. BACK CHECK VALVE – SMARTSITE™ NEEDLE-FREE SYSTEM.
388136	BD Gravity IV Set with Anti-Run Dry (ARD) Technology and AutoPrime. 3WAY STOPCOCK. INFUSION SET. VENTED. Gravity flow only.
R87 Sets – Gravity/Pressure Rated Sets *Legal Manufacturer: Becton Dickinson Infusion Therapy AB, Florettgatan 29C PO Box 631, Helsingborg, Sweden.*	
396350	R87P Luer-Lock IG-P
396351	R87P Luer-Lock IG-P
396353	R87 RLS Luer-Lock IG-P
396354	R87P Luer-Lock IG-P
396357	R87 RLS Luer-Lock IG-P
396361	R87 G Precision Luer-Lock IG-G
396363	R87 V Luer-Lock IG-P
396368	R87 V Luer-Lock IG-P
396370	R87 G Precision Luer-Lock IG-G
396373	R87 V Luer-Lock IG-P
396377	R87 V Luer-Lock IG-P
396392	R87 G Precision Luer-Lock IG-G
Gravity infusion sets	

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02008366189	Alaris™ Products. INFUSION SET. LOW SORBING. UNVENTED. 15 μm FILTER.
02008374189	Infusion set unvented. 15μm Filter
02008382189	Alaris™ Products. INFUSION SET. UNVENTED. NO FILTER.
03500100208	Alaris™ Products. INFUSION SET. VENTED. 15 μm FILTER.
MFX2309EV	SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 15 μm FILTER.
MFX2310EV	SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. LIGHT RESISTANT. LOW SORBING (TPU/EVA) VENTED. 15 μm FILTER.
MFX2311EV	SmartSite™ Needle-free System. MULTI-INFUSION SET. ONCOLOGY. VENTED. 0.2 μm FILTER.
03500304407	Alaris Products, Infusion Sets 15 μm Filter
03501410184	Universal Infusions set fur Druckinfusion
03508105208	Alaris™ Products. INFUSION SET. VENTED. 15 μm FILTER.
03508117442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15μm FILTER.
03508239442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15μm FILTER.
03508239448	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15μm FILTER.
03508240442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15μm FILTER.
03508241442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15μm FILTER.
03508242442	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. VENTED. 15μm FILTER.
03508317319	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 0.2 μm FILTER.
03508318429	Alaris™ Products. INFUSION SET. VENTED. 15 μm FILTER.
03508364318	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 15 μm FILTER.
03508370319	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 0.2 μm FILTER.
03508411318	Alaris™ Products. INFUSION SET. LIGHT RESISTANT. LOW SORBING. VENTED. 15 μm FILTER.
03508422208	Infusion set, Light resistant. Vented. 15 μm Filter
03508367318	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 15 μm FILTER.
Gravity blood sets	
12310100356	Transfusion/Blood Set. Unvented. 200 μm Filter.
12310100403	Transfusion set 200μm
12310105356	Transfusion/Blood Set. Unvented. 200 μm Filter.
12318381356	Transfusion/Blood Set. Unvented. 200 μm Filter.
12360100357	Transfusion/Blood Set. Vented. 200 μm Filter.
Secondary Sets	
MFX2300EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. LOW SORBING (TPU/EVA) LIGHT RESISTANT. VENTED. BACK CHECK VALVE.
MFX2301EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. VENTED. BACK CHECK VALVE.
MFX2302EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. VENTED. BACK CHECK VALVE. 0.2 μm FILTER.
MFX2303EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. LOW SORBING (TPU/EVA). LIGHT RESISTANT. VENTED. BACK CHECK VALVE. FLOW CONTROLLER.
MFX2304EV	Alaris™ Products. SmartSite™ Needle-free System. SECONDARY SET. ONCOLOGY. MALE TO MALE. BACK CHECK VALVE.
04108362X10	Multi-way Connecting Set.
72946NE	Secondary Set. Oncology. Vented. Light Resistant.
72946NEX10	Secondary Set. Oncology. Vented. Light Resistant.
72947NE	Secondary Set. Oncology. Unvented. Light Resistant. Back Check Valve.
72948NE	Secondary Set. Oncology. Unvented. Back Check Valve.
72949NE	Secondary Set. Oncology. Unvented. Back Check Valve.
72950NE	Secondary Set. Oncology. Unvented. Light Resistant. Back Check Valve.
72951NE	Secondary Set. Oncology. Unvented. Back Check Valve.
72951NEX10	Secondary Set. Oncology. Unvented. Back Check Valve.
72961NE	Secondary Set. Oncology. Vented. Back Check Valve.
72978NE	Secondary Set. Oncology. Vented. 0.2 μm Filter.
72979NE	Secondary Set. Oncology. Vented. 0.2 μm Filter.
72981NE	Secondary Set. Oncology. Vented. Back Check Valve.
72987NE	Secondary Set. Oncology. Light Resistant. Vented. Back Check Valve.

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72988NE	Secondary Set. Oncology. Vented. Back Check Valve. 0.2 µm Filter.
Secondary Sets: *Legal Manufacturer: Becton Dickinson and Company Limited, Pottery Road, Co. Dublin, Dun Laoghaire, Ireland*	
515302	SECONDARY SET (C61)
Flow controller sets	
03508060270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508067270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508068307	Alaris™ Products. INFUSION SET. LOW SORBING. VENTED. 15µm FILTER.
03508073270	Alaris™ Products. INFUSION SET. LOW SORBING. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508077270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508078270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508079270	Alaris™ Products. INFUSION SET. FLOW CONTROLLER. VENTED. 15µm FILTER.
03508080404	Alaris™ Products. SmartSite™ Needle-free System. MULTI-INFUSION SET. FLOW CONTROLLER. VENTED. 15 µm FILTER.
03508083440	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. FLOW CONTROLLER. VENTED. 15 µm FILTER.
03508084440	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. FLOW CONTROLLER. VENTED. 15 µm FILTER.
03508085440	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. FLOW CONTROLLER. VENTED. 15 µm FILTER.
04108060270	Alaris™ Products. EXTENSION SET. FLOW CONTROLLER.
04108064270	Alaris™ Products. EXTENSION SET. FLOW CONTROLLER.
04108073270	Alaris™ Products. EXTENSION SET. FLOW CONTROLLER.
04108074270	Alaris™ Products. EXTENSION SET. FLOW CONTROLLER.
04108078411	Alaris™ Products. SmartSite™ Needle-free System. EXTENSION SET. FLOW CONTROLLER.
Accessories and add-ons	
2305E	Multi-way Connecting Set
2306E	Multi-way Connecting Set
04108341419	Multi-way Connecting Set.
04108362418	Multi-way Connecting Set.
MFX2250EV	Alaris™ Products. SmartSite™ Needle-free System. BAG ACCESS DEVICE. VENTED.
04302243317	BD CHECK VALVE
04302260452	Anti-siphon valve
397015	FloPro
04000380192	Alaris™ Products. TRANSFER DEVICE
04002040071	Alaris Products Transfer Device
04302434353	Protection cap for female luer lock
04302398353	Injection site cap
TIVA Sets	
500-002V	Alaris™ Products. TIVA 2 WAY SET. ANTI-SIPHON VALVE. BACK CHECK VALVE.
500-003V	Alaris™ Products. TIVA 3 WAY SET. ANTI-SIPHON VALVES. BACK CHECK VALVE.
500-012V	Alaris™ Products. TIVA 2 WAY EXTENSION SET. ANTI-SIPHON VALVE. BACK CHECK VALVE.
500-013V	Alaris™ Products. TIVA 3 WAY EXTENSION SET. ANTI-SIPHON VALVES. BACK CHECK VALVE.
Administration & Catheter Extension Sets	
G40020B	Alaris™ Products. EXTENSION SET
G40320V	Alaris™ Products. EXTENSION SET. LIGHT RESISTANT.
500-021EV	Alaris™ Products. SmartSite™ Needle-free System. 2 WAY EXTENSION SET WITH CLAMPS
500-031EV	Alaris™ Products. SmartSite™ Needle-free System. 3 WAY EXTENSION SET WITH CLAMPS
MFX2203EV	Extension Set. Back Check Valve.
MFX2280EV	Extension Set. 3-Way Stopcock
MFX2283EV	Extension Set. 3-Way Stopcock
MFX2284EV	Extension Set. 3-Way Stopcock
04301433200	Alaris Products™. 4-WAY STOPCOCK
04301462200	Alaris Products™. 4-WAY STOPCOCK
04301463200	Alaris Products™. 4-WAY STOPCOCK
04103215162	Extension Set
04103220162	Extension Set

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04100002162	Alaris Products Extension set
04100006162	Extension Set
04100008162	Extension Set
04100010162	Extension Set
04100015162	Extension Set
04100020162	Extension Set
04100135162	Alaris™ Products. EXTENSION SET. Gravity flow only.
04100146162	Alaris™ Products. EXTENSION SET. Gravity flow only.
04100215162	Extension Set
04100401162	Extension Set. 4-way Stopcock.
04100403162	Extension Set. 4-way Stopcock.
04100405162	Extension Set. 4-way Stopcock.
04100410162	Extension Set. 4-way Stopcock.
04100415162	Extension Set. 4-way Stopcock.