
	Title: EU MDR Declaration of Conformity (MDR)	Page No. 1 of 5
	DoC Document No. STED500 – Alaris™ Gateway Workstation – EU MDR DoC	Revision No: 01

EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	BD Switzerland Sàrl Route de Crassier 17 Business Park Terre-Bonne Bâtiment A4 1262 Eysins Switzerland
Manufacturer SRN:	CH-MF-000026539
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road Drogheda, Co. Louth A92 YW26 Ireland
Authorised Representative SRN:	IE-AR-000007610
Product:	Alaris™ Gateway Workstation
Basic UDI-DI:	0885403CGPFDAJFV6
Risk Class and Rule:	Class IIb, Rule 9
Intended Purpose:	The Alaris™ Gateway Workstation is intended to be used within the hospital environment to provide mounting, power and communication support to the compatible Alaris™ infusion pumps. The Workstation transmits infusion data for the purpose of record keeping and pump alarm monitoring.
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands Notified Body Number: 2797

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product meets the provisions of the following Directives/ Regulation(s):

- Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices.
- Directive 2014/30/EU of the European Parliament and of the Council on Medical Devices relating to electromagnetic compatibility.
- Directive 2011/65/EU of the European Parliament and of the Council on the use of certain hazardous substances in electrical and electronic equipment including its amendment (EU) 2015/863.
- DIRECTIVE 2012/19/EU of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE)

	Title: EU MDR Declaration of Conformity (MDR)	Page No. 2 of 5
	DoC Document No. STED500 – Alaris™ Gateway Workstation – EU MDR DoC	Revision No: 01

Template GFM-10128EE

- Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.
- European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste
- Regulation (EU) 2023/1542 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC.
- Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices.

Conformity Assessment Route:

<input checked="" type="checkbox"/> ANNEX IX Chapter I and III – Quality management System	EC CERTIFICATE No.: MDR 745680
<input type="checkbox"/> ANNEX IX Chapter II - Technical Documentation	EC CERTIFICATE No.: N/A
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: N/A
<input type="checkbox"/> ANNEX XI Part A Production Quality Assurance	EC CERTIFICATE No.: N/A
<input type="checkbox"/> ANNEX XI Part B Product Verification	EC CERTIFICATE No.: N/A
<input type="checkbox"/> ANNEX II & III Technical Documentation	N/A


Common Specifications (CS):

Number: <Version/Year>	Title:	Full or Partial Application: <Justification>
N/A	N/A	N/A

Devices Covered by this DoC:

AGW v1.3.1

SKU#	Device Name	Device Class
80300UNS01-30	Alaris™ Gateway Workstation 3x0 Configuration without intelligent base unit	IIb
80300UNS01-32	Alaris™ Gateway Workstation 3x2 Configuration without intelligent base unit	IIb
80300UNS01-33	Alaris™ Gateway Workstation 3x3 Configuration without intelligent base unit	IIb
80300UNS01-34	Alaris™ Gateway Workstation 3x4 Configuration without intelligent base unit	IIb
80300UNS01-035	Alaris™ Gateway Workstation 0x3x5 Configuration without intelligent base unit	IIb


	Title: EU MDR Declaration of Conformity (MDR)	Page No. 3 of 5
	DoC Document No. STED500 – Alaris™ Gateway Workstation – EU MDR DoC	Revision No: 01

Template GFM-10128EE

80300UNS01-50	Alaris™ Gateway Workstation 5x0 Configuration without intelligent base unit	IIb
80300UNS01-52	Alaris™ Gateway Workstation 5x2 Configuration without intelligent base unit	IIb
80300UNS01-53	Alaris™ Gateway Workstation 5x3 Configuration without intelligent base unit	IIb
80300UNS01-54	Alaris™ Gateway Workstation 5x4 Configuration without intelligent base unit	IIb
80300UNS01-235	Alaris™ Gateway Workstation 2x3x5 Configuration without intelligent base unit	IIb
80300UNS01-70	Alaris™ Gateway Workstation 7x0 Configuration without intelligent base unit	IIb
80300UNS01-72	Alaris™ Gateway Workstation 7x2 Configuration without intelligent base unit	IIb
80300UNS01-73	Alaris™ Gateway Workstation 7x3 Configuration without intelligent base unit	IIb
80300UNS01-74	Alaris™ Gateway Workstation 7x4 Configuration without intelligent base unit	IIb
80300UNS01-92	Alaris™ Gateway Workstation 9x2 Configuration without intelligent base unit	IIb

AGW v1.3.2

SKU#	Device Name	Device Class
80300UNS02-30	Alaris™ Gateway Workstation 3x0 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-32	Alaris™ Gateway Workstation 3x2 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-33	Alaris™ Gateway Workstation 3x3 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-34	Alaris™ Gateway Workstation 3x4 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-035	Alaris™ Gateway Workstation 0x3x5 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-50	Alaris™ Gateway Workstation 5x0 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-52	Alaris™ Gateway Workstation 5x2 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-53	Alaris™ Gateway Workstation 5x3 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-54	Alaris™ Gateway Workstation 5x4 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-235	Alaris™ Gateway Workstation 2x3x5 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-70	Alaris™ Gateway Workstation 7x0 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-72	Alaris™ Gateway Workstation 7x2 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb


	Title: EU MDR Declaration of Conformity (MDR)	Page No. 4 of 5
	DoC Document No. STED500 – Alaris™ Gateway Workstation – EU MDR DoC	Revision No: 01

Template GFM-10128EE


80300UNS02-73	Alaris™ Gateway Workstation 7x3 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-74	Alaris™ Gateway Workstation 7x4 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb
80300UNS02-92	Alaris™ Gateway Workstation 9x2 Configuration with the wired Ethernet communication capability and bar code reader interface	IIb

AGW v1.6.1

SKU#	Device Name	Device Class
80223UNS02-30	Alaris™ Gateway Workstation 3x0 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-32	Alaris™ Gateway Workstation 3x2 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-33	Alaris™ Gateway Workstation 3x3 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-34	Alaris™ Gateway Workstation 3x4 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-035	Alaris™ Gateway Workstation 0x3x5 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-50	Alaris™ Gateway Workstation 5x0 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-52	Alaris™ Gateway Workstation 5x2 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-53	Alaris™ Gateway Workstation 5x3 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-54	Alaris™ Gateway Workstation 5x4 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-235	Alaris™ Gateway Workstation 2x3x5 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-70	Alaris™ Gateway Workstation 7x0 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-72	Alaris™ Gateway Workstation 7x2 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-73	Alaris™ Gateway Workstation 7x3 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-74	Alaris™ Gateway Workstation 7x4 Configuration with wired Ethernet connectivity to ACE	IIb
80223UNS02-92	Alaris™ Gateway Workstation 9x2 Configuration with wired Ethernet connectivity to ACE	IIb

	Title: EU MDR Declaration of Conformity (MDR)	Page No. 5 of 5
	DoC Document No. STED500 – Alaris™ Gateway Workstation – EU MDR DoC	Revision No: 01

Template GFM-10128EE

Authorised Signatory:	
Name & Title:	Michael A Campbell Senior Director Regulatory Affairs
On behalf of:	BD Switzerland Sàrl
Place of Issue:	Eysins, Switzerland
Date of Issue:	17-Jul-2025
Signature:	<div><div></div><div><div></div><div>Signed by: Signer Name: Michael Campbell Signing Reason: I approve this document Signing Time: 17-Jul-2025 5:47:51 AM PDT 6AF2B0DA9FF34F76A9B5EA01F0E98151</div></div></div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	New document created to meet MDR (EU) 2017/745 compliance.
02	Administration update only - Update to new template GFM-10128EE.