EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 52479**

Issued To: **Gambro Dasco S.p.A**
Medolla Facility
Via Modenese 66
Medolla (MO)
41036
Italy

In respect of:

The design, development and manufacture of sterile infusion lines and bloodline systems for use in haemodialysis, haemofiltration, haemodiafiltration and peritoneal dialysis treatment.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1999-10-21** Date: **2019-10-21** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 52479

Issued To:

Gambro Dasco S.p.A
Medolla Facility
Via Modenese 66
Medolla (MO)
41036
Italy

Number	Device Name	Intended purpose per IFU
Class IIb		
GMDN Code		
34999	Haemodialysis tubing set, single use	A collection of sterile items intended for the administration of haemodialysis. It will typically consist of a collection of tubing segments and, e.g., connectors or clamps, required to transport blood from/to a patient's vascular access device to/from the appropriate dialyser (haemodialyser) unit for processing or to transport other fluids to patient's vascular access device. This is a single-use device.
47334	Haemodialysis dialysate pyrogen filtration set	A collection of sterile devices designed to be used with a haemodialysis system for on-line filtration of the dialysate to remove bacteria and endotoxins during haemodialysis. This purified (filtered) dialysate is used for the replacement fluid (substitution solution). It includes tubing with an integrated filter(s), and typically connectors (e.g., Luer-lock) and a sampling port. This is a single-use device.

First Issued: **1999-10-21** Date: **2019-10-21** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 52479

Issued To:

Gambro Dasco S.p.A
Medolla Facility
Via Modenese 66
Medolla (MO)
41036
Italy

Class IIa		
NBOG Code		
MD 0102	Bloodlines and accessories for haemodialysis	----------

Class I (Sterile)		
NBOG Code		
MD 0102	Sterile accessories for haemodialysis	----------

First Issued: **1999-10-21** Date: **2019-10-21** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 52479**
Date:	**2019-10-21**
Issued To:	**Gambro Dasco S.p.A** **Medolla Facility** **Via Modenese 66** **Medolla (MO)** **41036** **Italy**

Subcontractor:	**Service(s) supplied**
Baxter Limited A47, Industrial Estate Marsa MRS3000 Malta	**Control of Sterilization** **Manufacture**
Bieffe Medital Manufacturing s.a.r.l. Route de Chebbaou Oued Ellil 2021 Tunisia	**Manufacture**
Bioiks D.O.O T/A Bioprod D.O.O. Stegne 11 1000 Ljubljana Slovenia	**Assembly** **Packaging** **Testing**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 52479**
Date:	**2019-10-21**
Issued To:	**Gambro Dasco S.p.A** **Medolla Facility** **Via Modenese 66** **Medolla (MO)** **41036** **Italy**

Subcontractor:	**Service(s) supplied**
Gambro Renal Products S.A. de C.V. Boulevard Pacifico No. 10014 Parque Industrial Pacifico Tijuana Baja California CP 22643 Mexico	**Control of Sterilization** **Manufacture**
Mediscan GmbH & Co KG Bad Haller Strasse 34 4550 Kremsmünster Austria	**E Beam Sterilization** **Gamma Irradiation**
Sterigenics Italy S.p.A Via Marzabotto, 4 Minerbio (BO) 40061 Italy	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 52479**
Date:	**2019-10-21**
Issued To:	**Gambro Dasco S.p.A** **Medolla Facility** **Via Modenese 66** **Medolla (MO)** **41036** **Italy**

Subcontractor:	**Service(s) supplied**
Steril Verona S.r.l. Via Fontana, 3 Nogara Verona 37054 Italy	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 52479**
Date: **2019-10-21**
Issued To: **Gambro Dasco S.p.A**
Medolla Facility
Via Modenese 66
Medolla (MO)
41036
Italy

Date	Reference Number	Action
21 October 1999		First Issue.
14 January 2001		Addition of subcontractor.
05 October 2001		Addition of subcontractor.
22 November 2002		Addition of subcontractor.
02 July 2003		Removal of Bioster subcontractor at Reggilo, Seriate and Caravaggio. The addition of Bioster subcontractor at Matova, Bergame and Padova.
22 October 2004		5 Year renewal.
31 March 2005		Addition of 'peritoneal dialysis treatment' to the scope of certificate. The change of subcontractor address details for Gambro Dasco SpA Via Appia.
08 November 2005		Redefine subcontractor activities and addition of Bioiks D.O.O. to subcontractor listing.
27 September 2006		Addition of 'Bioster SpA, 24068 Seriate' to list of significant subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 52479**
Date: **2019-10-21**
Issued To: **Gambro Dasco S.p.A**
Medolla Facility
Via Modenese 66
Medolla (MO)
41036
Italy

Date	Reference Number	Action
06 November 2008	7285982	The addition of 'Haemofiltration and Haemodiafiltration' to the scope of the certificate. The deletion of Gambro Medical Products Shanghai, Gambro Dasco, Latina Scalo and Midial as significant subcontractors. The name of Gambro Meopta subcontractor has changed to Gambro Czech Republic s.r.o. following the new business name. The addition of Gammarad as a significant subcontractor for Gamma irradiation.
15 October 2009	7297008	Certificate renewal. Change of address for the significant sub-contractor 'Gemmarad Italia S.P.A.'
11 August 2010	7549084	Addition of MEDISCAN GmbH & Co KG to the list of significant sub contractors for E-beam sterilization and gamma irradiation.
27 July 2011	7708906	Addition of Steril Verona S.r.l to the list of significant subcontractors for ETO sterilisation services for medical devices.
20 July 2012	7865589	Addition of subcontractor Gambro Renal Products S.A. de C.V for service of sterile manufacture.
16 July 2013	8023727	Reissue due to addition of Gambro Dasco S.p.A Poggio Rusco facility for manufacture and Bioster S.p.A. for E beam Sterilization to the list of significant subcontractors.
28 August 2014	8179881	Certificate Renewal.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 52479**

Date: **2019-10-21**

Issued To: **Gambro Dasco S.p.A**
Medolla Facility
Via Modenese 66
Medolla (MO)
41036
Italy

Date	Reference Number	Action
18 January 2016	8438612	Update to subcontractor information.
20 April 2016	8514873	Removal of subcontractor Gambro Dasco S.p.A, Poggio Rusco (MN).
01 September 2016	8588617	Removal of significant subcontractors Bioster S.p.A, Seriate; Bioster S.p.A, Mantova and Bioster S.p.A, Bergamo. Significant subcontractors name change from Bioster S.p.A, Poggio Rusco (MN) to Steris S.p.A, Poggio Rusco (MN) and Bioster S.p.A, Bastia di Rovolon (Padova) to Steris S.p.A, Bastia di Rovolon (Padova).
11 October 2017	8778680	Removal of significant subcontractors Gambro Czech Republic s.r.o. and Steris S.p.A. Update of significant subcontractor address for Steril Verona S.r.l. Addition of significant subcontractors Bieffe Medital Manufacturing s.a.r.l. and Baxter Limited.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 52479**
Date: **2019-10-21**
Issued To: **Gambro Dasco S.p.A**
Medolla Facility
Via Modenese 66
Medolla (MO)
41036
Italy

Date	Reference Number	Action
10 July 2018	8890414	Addition of subcontractor Baxter Deutschland GmbH, Edisonstr. 4, Unterschleißheim, 85716, Germany for Regulatory Compliance.
08 March 2019	7780196	Traceable to NB 0086.
14 June 2019	7780196	Change to service(s) provided by the subcontractors; 1) Baxter Limited – Malta, 2) Bieffe Medital Manufacturing s.a.r.l – Tunisia and 3) Gambro Renal Products S.A. de C.V. – Mexico. The removal of subcontractor Steris S.p.A, Via A, Piva, Poggio Rusco (MN), 46025, Italy Addition of supplement information
Current	3058762	Removed subcontractor Baxter Deutschland GmbH, Edisonstr. 4, UnterschleiBheim, 85716, Germany for Regulatory Compliance. Certificate Renewal.

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Legal Manufacturer Name: Gambro Dasco S.p.A

Legal Manufacturer Address: Via Modenese 66 Medolla (MO)

Legal Manufacturer Single Registration Number (SRN): IT-MF-000011224

Authorised Representative Name (if applicable): Not Required

Authorised Representative Address: Not Required

Authorised Representative Single Registration Number (SRN): Not Required

Notified Body Name and Address: BSI Group, The Netherlands B.V. Say Building, John M. Keynesplein 9,1066 EP Amsterdam, The Netherlands

Notified Body Identification Number: 2797

MDD Certificate Number: CE 52479

Original expiry date as indicated on the MDD Certificate prior to the extension of the validity: 2024-05-26

End date of extended validity/transition period [1]: 31 December 2028

[1] according to Article 120 3a, as amended by Regulation (EU) 2023/607 (MDR).

+++ We, as the legal manufacturer declare under our sole responsibility:

- for the above listed **MDD Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*
- the listed **device(s)** and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions: +++

This declaration is made on the following basis:

1. The Directive 93/42/EEC (MDD) certificate(s) covering the listed devices was valid on 26 May 2021.
2. The device(s) continue to comply with Directive 93/42/EEC (MDD)
3. The device does not undergo a significant change in the design and intended purpose from 26 May 2021.
4. The device(s) do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
5. Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

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6. A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) is put in place by the manufacturer no later than 26 May 2024.

7. A formal application in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made to the notified body for the device(s) listed on this declaration or has been made in respect of a device intended to substitute a device listed on this declaration, no later than 26 May 2024 and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) no later than 26 September 2024.

Product/Trade Name and Product Code or REF. number: *Refer to Appendix A*

Device MDR Risk Class: IIa, IIb and Is

Authorised Signatory:	
Name and Title:	Cristiano Salvadeo
Function:	General Mgr, Plant Medolla
Place of Issue:	Medolla
Date of Issue:	
Signature:	*Electronically signed by: Cristiano Salvadeo* *Reason: I approve this document* *Date: Mar 5, 2024 10:57 GMT+1*

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

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Appendix A: List of medical devices from MDD DoC or PCL

Product Code or REF number	Product or Trade Name
955599	ULTRALINE HDF
955600	ULTRALINE HD
115283	Ultra HDF Line
955037	ULTRA HDF Post Line
955528	PHYSIOSET ULTRA HDF Line
955490	ULTRA Prime Line
955529	PHYSIOSET ULTRA Prime Line
955408	ULTRA HDF Line
114533	ArtiSet HD SN HC
113898	evoset AFB K infusion
955077	ArtiSet PrePost
955075	ARTISET HD DNL HC
955526	PHYSIOSET HD DNL HC
955527	PHYSIOSET PRE-POST
955549	ARTISET HD DNL HC
955398	ARTISET HD DNL HC
955397	ARTISET PREPOST
955718	ARTISET HD DNL HC
6038475	SP-C35

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Product Code or REF number	Product or Trade Name
6038020	SP-C13
6033732	SP-339G
6038533	SP-27
6039259	SP-221
6039085	SP-176
6431233B	S-660-C
6431258	S-1016
6031090A	I201
6031058	H102-C
6430771A	C705
6039333A	SP-235
6031348A	I202
115648	GMB-SP06 ACCESSORY SAMPLE BAG

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Appendix B: Relationship Between MDD and MDR Codes

MDD product Code or REF number	MDD Product or Trade Name	MDR Product Code or REF Number (If the MDR device is a substitute[2] of the MDD device please include the word "substitute")	MDR Product or Trade Name	MDR Notified Body	MDR Legal Manufacturer
955599	ULTRALINE HDF	955599	ULTRALINE HDF	TUV Sud	Vantive Health GmbH
955600	ULTRALINE HD	955600	ULTRALINE HD	TUV Sud	Vantive Health GmbH
115283	Ultra HDF Line	115283	Ultra HDF Line	TUV Sud	Vantive Health GmbH
955037	ULTRA HDF Post Line	955037	ULTRA HDF Post Line	TUV Sud	Vantive Health GmbH
955528	PHYSIOSET ULTRA HDF Line	955528	PHYSIOSET ULTRA HDF Line	TUV Sud	Vantive Health GmbH
955490	ULTRA Prime Line	955490	ULTRA Prime Line	TUV Sud	Vantive Health GmbH
955529	PHYSIOSET ULTRA Prime Line	955529	PHYSIOSET ULTRA Prime Line	TUV Sud	Vantive Health GmbH
955408	ARTISET ULTRA HDF Line	955408	ARTISET ULTRA HDF Line	TUV Sud	Vantive Health GmbH
114533	ArtiSet HD SN HC	114533	ArtiSet HD SN HC	TUV Sud	Vantive Health GmbH
113898	evoset AFB K infusion	113898	evoset AFB K infusion	TUV Sud	Vantive Health GmbH

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

MDD product Code or REF number	MDD Product or Trade Name	MDR Product Code or REF Number (If the MDR device is a substitute[2] of the MDD device please include the word "substitute")	MDR Product or Trade Name	MDR Notified Body	MDR Legal Manufacturer
955077	ArtiSet PrePost	955077	ArtiSet PrePost	TUV Sud	Vantive Health GmbH
955075	ARTISET HD DNL HC	955075	ARTISET HD DNL HC	TUV Sud	Vantive Health GmbH
955526	PHYSIOSET HD DNL HC	955526	PHYSIOSET HD DNL HC	TUV Sud	Vantive Health GmbH
955527	PHYSIOSET PRE-POST	955527	PHYSIOSET PRE-POST	TUV Sud	Vantive Health GmbH
955549	ARTISET HD DNL HC	955549	ARTISET HD DNL HC	TUV Sud	Vantive Health GmbH
955398	ARTISET HD DNL HC	955398	ARTISET HD DNL HC	TUV Sud	Vantive Health GmbH
955397	ARTISET PREPOST	955397	ARTISET PREPOST	TUV Sud	Vantive Health GmbH
955718	ARTISET HD DNL HC	955718	ARTISET HD DNL HC	TUV Sud	Vantive Health GmbH
6038475	SP-C35	106024	SP-C35 PRESSURE TRANSDUCER PROTECTOR	TUV Sud	Vantive Health GmbH
6038020	SP-C13	101593	SP-C13 ACCESSORY SPIKE	TUV Sud	Vantive Health GmbH
6033732	SP-339G	107472	SP-339G ACCESSORY RE-INFUSION LINE	TUV Sud	Vantive Health GmbH

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

MDD product Code or REF number	MDD Product or Trade Name	MDR Product Code or REF Number (If the MDR device is a substitute[2] of the MDD device please include the word "substitute")	MDR Product or Trade Name	MDR Notified Body	MDR Legal Manufacturer
6038533	SP-27	101957	SP-27 ACCESSORY ADAPTOR	TUV Sud	Vantive Health GmbH
6039259	SP-221	100583	SP-221 PRESSURE TRANSDUCER PROTECTOR	TUV Sud	Vantive Health GmbH
6039085	SP-176	101422	SP-176 ACCESSORY SPIKE	TUV Sud	Vantive Health GmbH
6431233B	S-660-C	101354	S-660-C ACCESSORY "Y" CONNECTOR	TUV Sud	Vantive Health GmbH
6431258	S-1016	101023	S-1016 ACCESSORY CONNECTOR	TUV Sud	Vantive Health GmbH
6031090A	I201	105889	I201 ACCESSORY RE-INFUSION LINE	TUV Sud	Vantive Health GmbH
6031058	H102-C	105767	H102-C ACCESSORY HEPARIN LINE	TUV Sud	Vantive Health GmbH
115648	GMB-SP06 ACCESSORY SAMPLE BAG	115648	GMB-SP06 ACCESSORY SAMPLE BAG	TUV Sud	Vantive Health GmbH
6430771A	C705	101739	C-705 ACCESSORY EXPANSION CHAMBER	TUV Sud	Vantive Health GmbH

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

MDD product Code or REF number	MDD Product or Trade Name	MDR Product Code or REF Number (If the MDR device is a substitute[2] of the MDD device please include the word "substitute")	MDR Product or Trade Name	MDR Notified Body	MDR Legal Manufacturer
6039333A	SP-235	103223	SP-235 ACCESSORY RE-INFUSION LINE	TUV Sud	Vantive Health GmbH
6031348A	I202	105890	I202 ACCESSORY RE-INFUSION LINE	TUV Sud	Vantive Health GmbH

[2] Refers to procedure GQP-09-27 for a definition of substitute device

Product Service

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TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Baxter Healthcare SA
Thurgauerstrasse 130
8152 GLATTPARK (OPFIKON)
SWITZERLAND

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
56740	713264555, 713293967	+393476784153 anna.morandini@tuvsud.com		2024-02-14	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 056740 0055 Rev. 00

Reference: 713264555 | 713293967

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 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have 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 above stated manufacturer with the following SRN Number:

SRN Number: **CH-MF-000026124**

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 TÜV SÜD Product Service GmbH 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 TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

Product Service

If 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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 056740 0055 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-02-14

TÜV SÜD Product Service GmbH
Medical and Health Services

Anna Morandini
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Mira Fischer
Application Reviewer

Product Service

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH 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 during application review)	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

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> 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 during application review)	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
Prismaflex M60/M100/ M150 sets 00854120000000000000064JC **Prismaflex ST60/ ST100/ ST150 sets** 00854120000000000000064JC **Prismaflex HF20 Set** 00854120000000000000612JP **Prismaflex HF1000/1400 sets** 00854120000000000000611JM	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # CE93142; NB# 2797 BSI Group The Netherlands B.V. Originally issued to company **Gambro Industries** **7, Avenue Lionel Terray** **BP 126** **69883 Meyzieu Cedex** **France** which is part of the larger organization of Baxter Healthcare Corporation Therefore, additional transitional provisions are granted based on EU Commission's Q&A on pratical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
			State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Revaclear 300/ 400/ 500 00854120000000000000073JD **Theranova 400/ 500** 00854120000000000000069JN **Polyflux 14L/ 17L/ 21L** 00854120000000000000164JH **Polyflux 140H/ 170H/ 210H** **00854120000000000000065JE** **Polyflux 2H** 00854120000000000000168JR **Polyflux 6H** **00854120000000000000163JF** **Theralite** 0085412GMDN000000000616XK	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #CE 00393; NB#2797 BSI Group The Netherlands B.V. Originally issued to company **Gambro Dialysatoren GmbH** **Holger-Crafoord-Strasse 26** **72379 Hechingen** **Germany** which is part of the larger organization of Baxter Healthcare Corporation Therefore, additional transitional provisions are granted based on EU Commission's Q&A on pratical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Product Service

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
U9000 Plus 00854120000000000000072JB	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #CE 00393; NB#2797 BSI Group The Netherlands B.V. Originally issued to company **Gambro Dialysatoren GmbH** **Holger-Crafoord-Strasse 26** **72379 Hechingen** **Germany** which is part of the larger organization of Baxter Healthcare Corporation Therefore, additional transitional provisions are granted based on EU Commission's Q&A on pratical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2 or ☐ N/A - Device did not require a Notified Body certificate under Directives or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/02/14	713264555, 713293967	Initial issue

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 056740 0017 Rev. 00

Manufacturer:

Baxter Healthcare SA
Thurgauerstrasse 130
8152 Glattpark (Opfikon)
SWITZERLAND

SRN Manufacturer: CH-MF-000026124

Authorized Representative:

Baxter Deutschland GmbH
Edisonstrasse 4, 85716 Unterschleissheim, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G12 056740 0017 Rev. 00

Report No.: ITA1769512

Valid from: 2022-10-20
Valid until: 2027-10-19

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-10-20

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Implantable Class IIb Devices and Class III Devices)

No. G12 056740 0017 Rev. 00

Classification:	III
Device Group:	F010604 - DIALYSERS FOR SPECIAL HAEMODIAFILTRATION AND OTHER THERAPIES
Intended Purpose:	Refer to the Combined Certificate G70
The validity of this certificate depends on conditions and/or is limited to the following:	Not applicable

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 056740 0024 Rev. 00

Manufacturer:

Baxter Healthcare SA
Thurgauerstrasse 130
8152 Glattpark (Opfikon)
SWITZERLAND

SRN Manufacturer: CH-MF-000026124

Authorized Representative:

Baxter Deutschland GmbH
Edisonstrasse 4, 85716 Unterschleissheim, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 056740 0024 Rev. 00

Report No.: ITA1895838

Valid from: 2023-01-18
Valid until: 2028-01-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-01-18

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 056740 0024 Rev. 00

Classification:	IIb
Device Group:	F040101 - DIALYSIS CONCENTRATES, ACID SOLUTIONS, NON-STERILE
Intended Purpose:	Acid concentrate intended for on-line preparation of hemodialysis, hemodiafiltration or hemofiltration fluids.

Classification:	IIb
Device Group:	F040201 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, POWDER
Intended Purpose:	Dry concentrate intended for preparation of hemodialysis solutions, hemodiafiltration and hemofiltration substitution fluids.

Classification:	IIb
Device Group:	F040302 - DIALYSIS CONCENTRATES, WITHOUT ACETATE BUFFER - AFB
Intended Purpose:	Intended to be used as a concentrated electrolyte solution in preparation of hemodialysis fluids without buffer in Acetate-Free Biofiltration (AFB) and with a potassium concentration profile.

The validity of this certificate depends on conditions and/or is limited to the following:	Not applicable

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TÜV®

MDR EU Declaration of Conformity

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

According to:	**Regulation (EU) 2017/745 (MDR)**
Conformity Assessment Description/Annexes: **Annex IX excluding Chapter II**	
Notified Body Certificate(s): **G10 056740 0024 Rev.00** Expiry date of the Notified Body Certificate(s): 2028-01-17	
Notified Body's name and address: **TÜV SÜD Product Service GmbH** **Ridlerstraße 65, 80339 Munich** **Germany** Notified Body's identification number: **0123**	
Manufacturer's Single Registration Number (SRN): **CH-MF-000026124**	
Manufacturer's name: **Baxter Healthcare SA**	
Manufacturer's address: **Thurgauerstrasse 130** **8152 Glattpark (Opfikon)** **Switzerland**	
EC Authorized Representative's Name, Address, and SRN: **Baxter Deutschland GmbH** **Edisonstraße 4, 85716 Unterschleißheim** **Germany** **SRN: DE-AR-000010308**	
+++ We declare under our sole responsibility that the following product(s) conform to the applicable provisions of the above-mentioned Regulation, Union Registration(s) and Common Specifications(s) +++	
Product or Trade Name and Code/Catalog Number(s): **Refer to Product Code List**	
Intended Purpose(s)/Use(s):. **Refer to Product Code List**	
Product Basic UDI-DI Number: **Refer to Product Code List**	
Device Risk Class: **IIb**	
Common Specifications Applied: Not Applicable	
Other relevant Union Legislation that the device is in conformity with: Not Applicable	

MDR EU Declaration of Conformity

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

+++ This declaration is made on the following basis:

- For devices with an EC Certificate issued by a Notified Body:
  - The validity of this document shall not start earlier than the validity date of the corresponding EC Certificate.
  - The DoC declares conformity to all product lots released within the validity period/dates of the corresponding EC Certificate.
- For Class I devices (that are non-sterile, have no measurement function or are not reusable surgical instruments) the DoC declares conformity to the product lots released after the date of signature.
- Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).
- Additional information may be attached/appended to this template, such as common specifications, compliance to other union regulations/registrations, product code list or any other supporting information. +++

Signature: _____Fabrizio Pasqua VP Quality_____ __Zurich 20/01/2023

(Name, Title/Function) *(Place, Date)*

CE-Marked Product Code List (PCL) to the EU Declaration of Conformity

Business: Renal Care

MDR EU Certificate(s) Reference	**G10 056740 0024 Rev.00**
Conformity Assessment Description/Annexes:	Annex IX excluding Chapter II
Device Risk Class:	IIb
Sterilization Method(s):	Not Applicable (non-sterile products)
Sterilization Facility/Facilities:	Not Applicable
Manufacturing Facility/Facilities:	Gambro Dasco S.p.A Via Modenese 66 Medolla (MO) 41036 Italy

CE-Marked Product Code List (PCL) to the EU Declaration of Conformity

Product Code or REF. number	Product or Trade Name	Intended Purpose/Use	Basic UDI-DI	STED ID Number	Date of initial MDR CE Marking
955830	BiCart 650	The BiCart product is intended for preparation of hemodialysis solutions. The BiCart cartridge is also intended for preparation of hemodiafiltration and hemofiltration substitution fluids. Preparation of substitution fluids for hemodiafiltration and hemofiltration has not been cleared in the USA. The BiCart product must always be used together with a suitable acid concentrate.	00854120000000000000106J3	STED-MDR-R-0058	20 Jan 2023
955831	BiCart 650				
955832	BiCart 650				
955833	BiCart 720				
955834	BiCart 720				
955837	BiCart 720				
109733	BiCart 720				
955839	BiCart 1150				
955840	BiCart 1150				
955841	BiCart 1150				
955843	BiCart 1250				
114014	BiCart 1250				
955845	BiCart 1250				
955846	BiCart 1250				
955847	BiCart Select combi-pak	The BiCart and SelectCart products are intended for preparation of hemodialysis solutions and, when used on compatible Baxter/Gambro dialysis systems, hemodiafiltration and hemofiltration substitution fluids. The BiCart and SelectCart products must always be used together with a suitable acid-component concentrate	00854120000000000000107J5	STED-MDR-R-0058,	20 Jan 2023
955848	BiCart Select combi-pak				
955852	BiCart Select combi-pak				

This Product Code List has been reviewed and verified by: Cinzia Tamani Date: 14 DEC 2023
(Name/Surname/Signature)
Title: Global Regulatory Lead

EU Declaration of Conformity (DoC)

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

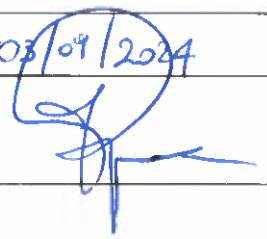
Manufacturer Name and Address: **Vantive Health GmbH** **Thurgauerstrasse 130,** **8152 Glattpark (Opfikon),** **Switzerland** Manufacturer Single Registration Number (SRN): **CH-MF-000038981**
Authorised Representative Name and Address: **Vantive S.r.l.** **Via del Serafico 89,** **00142 Rome** **Italy** Authorised Representative Single Registration Number (SRN): **IT-AR-000041309**
+++ We as Manufacturer declare, under our sole responsibility, that the product(s) listed below conform to the applicable provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and the following Directive(s), Regulation(s) and Common Specification(s). +++
Other relevant Directives, Regulations and Union Legislations that the device is in conformity with: **Not Applicable**
Common Specifications Applied: **N/A**
Product/Trade Name and Product Code or REF. number: **Refer to Product Code List**
Intended Purpose/Use: **Refer to Product Code List**
Device Risk Class: **I**
Product Basic UDI-DI Number: **Refer to Product Code List**
MDR EU Certificate(s) No.: **N/A**
Conformity Assessment Description/Annexes: **Annex II and Annex III**
Notified Body Name and Address: **N/A** Notified Body Identification Number: **N/A**
+++ This Declaration is made on the following basis: • For devices with a MDR EU Certificate issued by a Notified Body:

EU Declaration of Conformity (DoC)

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

- The validity of this document shall not start earlier than the validity date of the corresponding MDR EU Certificate.
- The DoC declares conformity to all product lots released within the validity period/dates of the corresponding MDR EU Certificate.

- For Class I devices (*that are non-sterile, have no measurement function or are not reusable surgical instruments*) the DoC declares conformity to the product lots released after the date of signature.
- Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).
- Additional information may be attached/appended to this template, such as common specifications, compliance to other union regulations/registrations, product code list or any other supporting information. +++

Authorised Signatory:	
Name and Title:	Fabrizio Pasqua
Function:	Vice President Quality and Regulatory Global
Place of Issue:	Zurich
Date of Issue:	03/09/2024
Signature:	

CE-Marked Product Code List (PCL) to the EU Declaration of Conformity

Business: Renal Care

MDR EU Certificate(s) Reference:	Not Applicable
Conformity Assessment Description/Annexes:	Annex II and Annex III
Device Risk Class:	I
Sterilization Method(s):	Not Applicable (non-sterile products)
Sterilization Facility/Facilities:	Not Applicable
Manufacturing Facility/Facilities:	Gambro Dasco S.p.A Via Modenese 66 Medolla (MO) 41036 Italy

CE-Marked Product Code List (PCL) to the EU Declaration of Conformity

Product Code or REF. number	Product or Trade Name	Intended Purpose/Use	Basic UDI-DI	STED ID Number	Date of initial MDR CE Marking
955850	CleanCart A	The CleanCart A cartridge is intended for preparation of a sodium carbonate solution used for removing organic deposits, fats and proteins, from the dialysis machine's fluid circuit. The CleanCart A cartridge must be used in combination with the heat disinfection program of the corresponding dialysis machine.	7332414VA00003634	STED-MDR-R-0003	3 Sept 2024
114012					
955851	CleanCart C	The CleanCart C cartridge is intended for preparation of a citric acid solution used for removing calcium and magnesium precipitation from the dialysis machine's fluid circuit. The CleanCart C cartridge must be used in combination with the heat disinfection program of the corresponding dialysis machine.	7332414VA00003736		
114013					

This Product Code List has been reviewed and verified by: Cinzia Tamani Date: 3rd SEPT 2024
(*Name/Surname/Signature*)

Title: *Global Regulatory Lead*

MDR EU Declaration of Conformity

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

According to:	**Regulation (EU) 2017/745 (MDR)**
Conformity Assessment Description/Annexes: **Annex IX excluding Chapter II**	
Notified Body Certificate(s): **G10 056740 0024 Rev.00** Expiry date of the Notified Body Certificate(s): 2028-01-17	
Notified Body's name and address: **TÜV SÜD Product Service GmbH** **Ridlerstraße 65, 80339 Munich** **Germany** Notified Body's identification number: **0123**	
Manufacturer's Single Registration Number (SRN): **CH-MF-000026124**	
Manufacturer's name: **Baxter Healthcare SA**	
Manufacturer's address: **Thurgauerstrasse 130** **8152 Glattpark (Opfikon)** **Switzerland**	
EC Authorized Representative's Name, Address, and SRN: **Baxter Deutschland GmbH** **Edisonstraße 4, 85716 Unterschleißheim** **Germany** **SRN: DE-AR-000010308**	
+++ We declare under our sole responsibility that the following product(s) conform to the applicable provisions of the above-mentioned Regulation, Union Registration(s) and Common Specifications(s) +++	
Product or Trade Name and Code/Catalog Number(s): **Refer to Product Code List**	
Intended Purpose(s)/Use(s):. **Refer to Product Code List**	
Product Basic UDI-DI Number: **Refer to Product Code List**	
Device Risk Class: **IIb**	
Common Specifications Applied: Not Applicable	
Other relevant Union Legislation that the device is in conformity with: Not Applicable	

MDR EU Declaration of Conformity

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

+++ This declaration is made on the following basis:

- For devices with an EC Certificate issued by a Notified Body:
  - The validity of this document shall not start earlier than the validity date of the corresponding EC Certificate.
  - The DoC declares conformity to all product lots released within the validity period/dates of the corresponding EC Certificate.
- For Class I devices (that are non-sterile, have no measurement function or are not reusable surgical instruments) the DoC declares conformity to the product lots released after the date of signature.
- Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).
- Additional information may be attached/appended to this template, such as common specifications, compliance to other union regulations/registrations, product code list or any other supporting information. +++

Signature: _____Fabrizio Pasqua VP Quality_____ __Zurich 20/01/2023

(Name, Title/Function) *(Place, Date)*

CE-Marked Product Code List (PCL) to the EU Declaration of Conformity

Business: Renal Care

MDR EU Certificate(s) Reference	**G10 056740 0024 Rev.00**
Conformity Assessment Description/Annexes:	Annex IX excluding Chapter II
Device Risk Class:	IIb
Sterilization Method(s):	Not Applicable (non-sterile products)
Sterilization Facility/Facilities:	Not Applicable
Manufacturing Facility/Facilities:	Gambro Dasco S.p.A Via Modenese 66 Medolla (MO) 41036 Italy

CE-Marked Product Code List (PCL) to the EU Declaration of Conformity

Product Code or REF. number	Product or Trade Name	Intended Purpose/Use	Basic UDI-DI	STED ID Number	Date of initial MDR CE Marking
955830	BiCart 650	The BiCart product is intended for preparation of hemodialysis solutions. The BiCart cartridge is also intended for preparation of hemodiafiltration and hemofiltration substitution fluids. Preparation of substitution fluids for hemodiafiltration and hemofiltration has not been cleared in the USA. The BiCart product must always be used together with a suitable acid concentrate.	00854120000000000000106J3	STED-MDR-R-0058	20 Jan 2023
955831	BiCart 650				
955832	BiCart 650				
955833	BiCart 720				
955834	BiCart 720				
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955848	BiCart Select combi-pak				

This Product Code List has been reviewed and verified by: Cinzia Tamani Date: 13 MARCH 24

(Name/Surname/Signature)

Title: Global Regulatory Lead