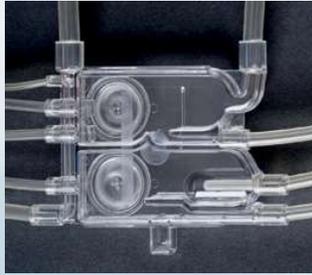


## ARTISET blood tubing system

### INTEGRATED BLOOD CIRCUIT FOR SIMPLICITY — IN JUST ONE MOVE

As a sponsor and leading investor in dialysis therapy, we present the ARTISET blood tubing system that also treatment ready for each satisfaction and operational efficiency compared to conventional blood tubing systems.

The ARTISET blood tubing system is an exclusive blood circuit designed to work with the **Artis Physio** system. Compared with conventional bloodlines, the compact and highly integrated design offers various important advantages both from a medical and handling perspective.



HD DM – ARTISET blood tubing system			
PRODUCT DESCRIPTION	CODE	DESCRIPTION	STERILIZATION
Accessories			
Hemodialyzer – Single head	9507065509	ARTISET 15 DM LC Gamma radiation	Gamma radiation
Safety Priming	9507065509	ARTISET 15 DM LC Gamma radiation	Gamma radiation
Ultra Prime	9507065509	ARTISET 15 DM LC Gamma radiation	Gamma radiation
Hemodialyzer – Double head	9507065509	ARTISET 15 DM LC Gamma radiation	Gamma radiation
Ultra Prime	9507065509	ARTISET 15 DM LC Gamma radiation	Gamma radiation

HD SM – ARTISET blood tubing system			
PRODUCT DESCRIPTION	CODE	DESCRIPTION	STERILIZATION
Accessories			
Hemodialyzer – Single head	114553	ARTISET 15 SM HC Gamma radiation	Gamma radiation
Safety Priming	114553	ARTISET 15 SM HC Gamma radiation	Gamma radiation
Ultra Prime	114553	ARTISET 15 SM HC Gamma radiation	Gamma radiation

### On-line HDF/HF in Pre/Post dilution – ARTISET blood tubing system

PRODUCT DESCRIPTION	CODE	DESCRIPTION	STERILIZATION
Accessories			
Hemodialyzer and concentrate	9507065509	ARTISET 15 DM LC Gamma radiation	Gamma radiation
Ultra Prime	9507065509	ARTISET 15 DM LC Gamma radiation	Gamma radiation

### On-line HDF in Post dilution – ARTISET blood tubing system

PRODUCT DESCRIPTION	CODE	DESCRIPTION	STERILIZATION
Accessories			
Hemodialyzer and concentrate	9507065509	ARTISET 15 DM LC Gamma radiation	Gamma radiation
Ultra Prime	9507065509	ARTISET 15 DM LC Gamma radiation	Gamma radiation

Note: A complete pack of either priming bags is recommended for each set. Both have a limited shelf life.

### Recommended spare accessories

PRODUCT DESCRIPTION	CODE	DESCRIPTION	STERILIZATION
Accessories			
Connectors to prime treatment	114376	Try Prime Double connector	Gamma radiation
Priming with ARTISET PREPLOT	103472	Primer Fill 50x200	Beta radiation

⚠ The full list of devices in this system can be found in the manual. Please contact your local representative for a complete list of devices. The code 9507065509 is a placeholder for the specific model. Please contact your local representative for further information.

Baxter Healthcare Corporation  
One Baxter Parkway  
Deerfield, IL 60015  
USA  
1-800-422-9837

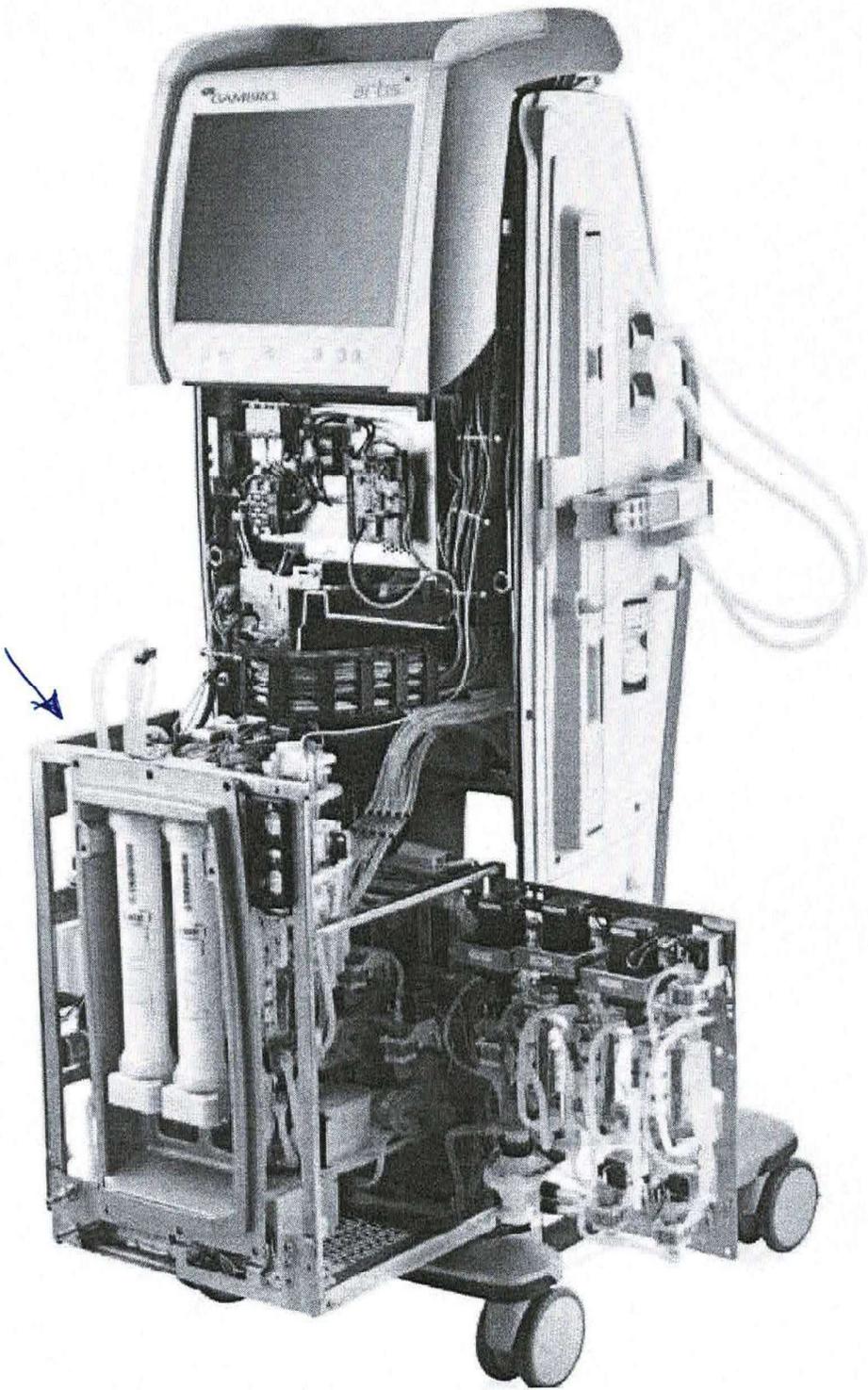
© 2014 Baxter International Inc. All rights reserved. Baxter International Inc. is the manufacturer of the ARTISET blood tubing system.

# artiset

blood tubing system





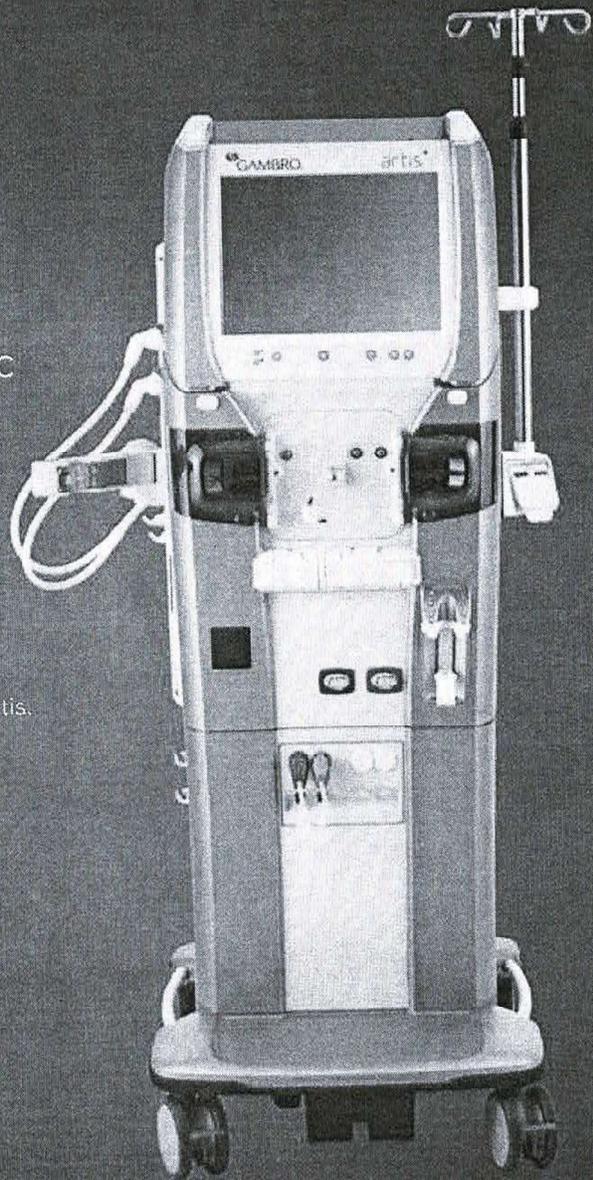


# Artis dialysis system – Advanced simplicity

## Making life in the dialysis clinic easier for everyone

We are pleased to introduce you to the next level of renal care. All patients will receive excellent individualized treatments delivered through advanced and innovative technologies that simplify everyday operations and enhance user experience.

Experience the benefits of advanced simplicity with Artis.



 **GAMBRO**®

# Artis dialysis system - Main performances



HCE N5361\_2 © 2008 11 - Gambro - Lunda AB

## Treatment modalities:

- HD DN and SN modes
- Isolated UF
- Designed for BiCart Select® system
- Ultrapure dialysis fluid
- Flexible and programmable heparin delivery

## ULTRA therapies®:

- Pressure-controlled on-line HDF
- Volume-controlled on-line HDF
- Sterile disposable ultrafilter for preparation of the substitution fluid

## Bio-controlled therapies:

- HEMO<sup>CONTROL</sup>™: HD with automatic sodium and UF profiling mode
- ULTRA<sup>CONTROL</sup>™: online HDF with automatic pressure-controlled mode

## Quality control modules

- **Prescription:** Programmable patient card or Exalis® network
- **BPM:** Blood pressure monitoring
- **Diascan™:** Real time measurement of the dialysis dose
- **Hemoscan™:** Real time measurement of the blood volume variation
- **Smartscan:** Real time assessment of the treatment settings
- **Dialysis reporting:** Real time treatment report table
- Connecting to **Exalis** for clinical data management

## System integration

- **ArtiSet** blood tubing system with auto-loading procedure
- **One button** auto-priming procedure
- **Evaclean:** integrated draining of priming fluid
- **NavPad** user interface navigation system
- **Automatic** wake-up and standby mode
- **Programmable** priming, rinseback and disinfection
- **Integrated** service mode

## General specifications

Dimensions	
Height	1550 mm
Width	500 to 660 mm
Depth of base	700 mm
Foot print	0.405 m <sup>2</sup>
Dry weight	130 kg

Electrical	
Voltage	110V - 240V AC (± 10%)
Frequency	50/60 Hz (± 5%)
Battery backup	Emergency power supply (up to 30 min)

Water supply requirements	
Refer to both local and AAMI standards for water quality	
Inlet pressure	150 to 800 kPa
Inlet temperature	+5 to +35 °C (230V) +10 to +35 °C (115V)

Blood management	
Real blood flow	10 to 500 ml/min
Blood pressure supervision	Arterial: -400 to +150 mmHg Venous: -100 to +450 mmHg System: -100 to +800 mmHg
Relative blood volume	-40% to +10%
Air detection	Ultrasonic air bubble detector
Heparin administration	1.5 to 10 ml/h infusion rates (linear or intermittent), with extra bolus
Blood leak detection	Infrared light
Blood pressure monitoring	+60 to +255 mmHg (systolic) +30 to +195 mmHg (diastolic) 30 to 200 bpm (heart rate)

Dialysis fluid preparation	
Temperature	+35.5 to +39.5 °C
Flow rate	300 to 800 ml/min, in steps of 50ml/min (± 2% of the set value)
[Na <sup>+</sup> ] range	130 to 160 mmol/L (± 2.5%)
[HCO <sub>3</sub> <sup>-</sup> ] range	24 to 38 mmol/L (± 5%)
Substitution fluid (on-line HDF)	1.2 to 27 L/h (maximum 100 L)

Fluid removal by ultrafiltration	
UF volume	0 to 24 L, in steps of 0.05L ± 2.5% or ± 50 ml/h of the set value, whichever is greater
UF rate	0 to 3 L/h

Hygiene	
Heat and chemical disinfection	
Integrated heat mode with Gambro CWP	
Heat with CleanCart® (cleaning, disinfection, decalcification)	
Disinfection programs history	
Bacteriostatic standby mode	

External connectivity	
Ethernet port 10/100 base T	
Plug for remote alarm control	
USB port for Gambro Service Operations	

Other features	
pH meter	
Connection to central concentrate supply	
Adjustable IV pole	
Removable top tray	
Back tray for permanent chemical jugs	

Operating environmental conditions	
Ambient temperature	+8 to +35 °C
Relative humidity	30 to 85%
Ambient pressure	795 to 1060 hPa

Gambro Lundia AB, PO Box 10101, SE-22010 Lund, Sweden  
Phone + 46 46 16 90 00, partner@gambro.com, www.gambro.com



1.3

1.5

# U9000™ ultrafilter

For ultrapure dialysis fluid

The U9000™ ultrafilter is central to the dialysis fluid delivery system:

- Purification of water for dialysis
- Preparation of ultrapure dialysis fluid
- Preparation of substitution fluid for on-line HDF/HF\*
- High bacterial and endotoxin retention capabilities
- Convenient disinfection\*\*



\* In combination with an additional single use ultrafilter with Gambro dialysis machines.

\*\* When the U9000 ultrafilter is used in combination with Gambro dialysis machines, only the disinfectants recommended in the machine operator manuals should be used. Furthermore, disinfection should follow the

 **GAMBRO**

# U9000™ ultrafilter

Specifications	
Components	Material
Membrane	PAES/PVP
Potting material	Polyurethane (PUR)
Housing and caps	Polycarbonate (PC)
Sealing	Silicone rubber
Protection caps	Polypropylene (PP) Polyethylene (PE)
Effective membrane area (m <sup>2</sup> )	2.4
Inner diameter (µm)	190
Wall thickness (µm)	45
Product code	N 50 480

Performance		
Filtration flow	At inlet pressure p <sub>in</sub> [mmHg]	
	37°C	5°C
Q <sub>F</sub> (mL/min)		
300	59	111
600	117	221
900	176	332
1200	235	443
Determined with 0.9% sodium chloride solution. Inlet pressure p <sub>in</sub> is measured at fluid entry Results may vary ± 10%		
Field of application		
Bacteria, pyrogen and particle filter for water and dialysis fluid		
Priming volume (ml)		
Lumen		135
Filtrate side		280
Typical retention values for bacteria and endotoxins		
Bacterial challenge: Pseudomonas diminuta ATCC 19146 in saline lactose broth. Cell diameter approx. 0.3 µm		LRV*  >7
Endotoxin challenge: E. coli O55:B5 endotoxin (Whittaker, USA)		>3.5
Disinfection**		
Chemical disinfection agents recommended for U9000 ultrafilter		
Peracetic acid (≤0.1%)		
Sodium carbonate (≤0.5%)		
Sodium hypochlorite (≤0.5%)		
Citric acid (≤2.0%)		

\* LRV = Logarithmic retention value  
LRV = log<sub>10</sub> (number of organisms in challenge suspension/number of organisms in filtrate)

\*\* The disinfection routine recommended in the dialysis machine operator manuals should be followed.

**CE 0086** This product is CE-marked in accordance with the requirements in EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Gambro® is a registered trademark of Gambro Lundia AB.  
U9000™ is a trademark of Gambro Lundia AB, registered in the European Union.

Gambro Lundia AB  
PO Box 10101  
SE-22010 Lund  
Sweden  
Phone +46 46 16 90 00  
partner@gambro.com



## 13.19 Ultrafilters Change Procedure

It is recommended to replace the U9000 ultrafilters following the instructions provided in the U9000 Ultrafilter Instruction for Use.

U9000 Ultrafilters can not tolerate more than twelve Chemical Disinfection programs with Hypochlorite.

U9000 Ultrafilters must be changed when the maximum allowed number of chemical disinfection programs with hypochlorite has been performed.

U9000 Ultrafilters can not tolerate more than 150 Disinfection programs, including both Heat and Chemical disinfections.

U9000 Ultrafilters must be changed when the maximum allowed number of disinfection programs has been performed.

U9000 Ultrafilters can not be used more than 90 days.

U9000 Ultrafilters must be changed when the maximum presetted number of days has expired.

It is possible to perform the Ultrafilter Change procedure anytime before booking or starting the priming procedure. However, the “Ultrafilters History” table will be always available during treatment, in the *Hygiene* sub-screen. To open this sub-screen, press the “Hygiene” button on the *Report* screen.

### **NOTE**

Use gloves when performing the ultrafilters change procedure.

To change the ultrafilters, proceed as follows:

1. In the Report screen, press the “Hygiene” button to open the *Hygiene* sub-screen;



Figure 13-7. Hygiene sub-screen

# 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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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI. This certificate was issued electronically and is bound by the conditions of the contract.

# 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
<b>Class IIb</b>		
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**

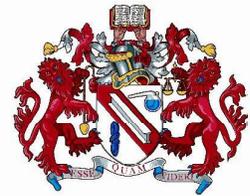
Expiry Date: **2024-05-26**

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Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



# 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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Page 3 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI. This certificate was issued electronically and is bound by the conditions of the contract.

# 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**

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

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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**

...making excellence a habit.™

# 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 subcontractor '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.

# 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, Unterschleißheim, 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 <sup>1</sup> : 31 December 2028 <sup>1</sup> according to Article 120 3a, as amended by Regulation (EU) 2023/607 (MDR).
+++ We, as the legal manufacturer declare under our sole responsibility: <ul style="list-style-type: none"><li>for the above listed <b>MDD Certificate</b> the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met <i>and/or</i></li><li>the listed <b>device(s)</b> 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,</li></ul> namely by fulfilling the following conditions: +++
This declaration is made on the following basis: <ol style="list-style-type: none"><li>The Directive 93/42/EEC (MDD) certificate(s) covering the listed devices was valid on 26 May 2021.</li><li>The device(s) continue to comply with Directive 93/42/EEC (MDD)</li><li>The device does not undergo a significant change in the design and intended purpose from 26 May 2021.</li><li>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.</li><li>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.</li></ol>

# 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).**

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: <i>Refer to Appendix A</i>
Device MDR Risk Class: IIa, IIb and Is

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

# 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 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).

<b>Product Code or REF number</b>	<b>Product or Trade Name</b>
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 <sup>2</sup> 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 <sup>2</sup> 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 <sup>2</sup> 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 <sup>2</sup> 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

<sup>2</sup> Refers to procedure GQP-09-27 for a definition of substitute device

# EC Certificate - Full Quality Assurance System

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

**No.** CE 52478  
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 renal replacement therapy equipment systems.**

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: **2019-12-20**

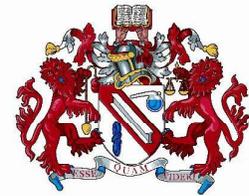
Expiry Date: **2024-05-26**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 52478

Issued To:

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

Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
<b>GMDN Code</b>		
34994	Hemodialysis system dialysate delivery unit	Hemodialysis System intended to perform intermittent Hemodialysis (HD), Hemofiltration (HF) and hemodiafiltration (HDF) therapies.

First Issued: **1999-10-21**

Date: **2019-12-20**

Expiry Date: **2024-05-26**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 52478**  
 Date: **2019-12-20**  
 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.
18 May 2001		Addition of products to certificate.
23 December 2004	4619927	Renewal of certificate and amendment of products listed on certificate.
08 January 2009	7304000	The removal of Prismaflex and the addition of Artis & Evosys devices.
20 February 2009	7297035	Minor name change from Gambro Dasco S.p.A. Monitor Division, A Division of Gambro Dasco S.p.A. to Gambro Dasco S.p.A. Monitor Facility.
14 December 2009	7457462	Certificate renewal. Minor change from 'Monitor Facility' to 'Medolla Facility' and the removal of the supplementary information.
16 July 2013	8023676	Addition of 'Gambro Dasco S.p.A. Crevalcore Facility' for manufacture and 'Gambro Dasco S.p.A. Modena Facility' for design and development to the list of significant subcontractors
08 December 2014	8192287	Certificate renewal
20 April 2016	8514873	Removal of subcontractors; Gambro Dasco S.p.A, Crevalcore and Gambro Dasco, S.p.A, Modena.
10 July 2018	8890419	Addition of subcontractor Baxter Deutschland GmbH, Edisonstr. 4, Unterschleißheim, 85716, Germany for Regulatory Compliance.

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 52478**  
 Date: **2019-12-20**  
 Issued To: **Gambro Dasco S.p.A.**  
**Medolla Facility**  
**Via Modenese 66**  
**Medolla (MO)**  
**41036**  
**Italy**

Date	Reference Number	Action
08 March 2019	7780196	Traceable to NB 0086.
Current	3058945	Removed subcontractor Baxter Deutschland GmbH, Edisonstr. 4, Unterschleibheim, 85716, Germany for Regulatory Compliance. Addition of supplementary information table. 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. Medolla facility Legal Manufacturer Address: Via Modenese 66, Medolla (MO) 41036 Italy Legal Manufacturer Single Registration Number (SRN): IT-MF-000011224
Authorised Representative Name (if applicable): Not applicable Authorised Representative Address: Not applicable Authorised Representative Single Registration Number (SRN): Not applicable
Notified Body Name and Address: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Notified Body Identification Number: 2797 MDD Certificate Number: CE 52478 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 <sup>1</sup> : 2028-12-31 <sup>1</sup> according to Article 120 3a, as amended by Regulation (EU) 2023/607 (MDR).
+++ We, as the legal manufacturer declare under our sole responsibility: <ul style="list-style-type: none"><li>for the above listed <b>MDD Certificate</b> the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met <i>and/or</i></li><li>the listed <b>device(s)</b> 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,</li></ul> namely by fulfilling the following conditions: +++
This declaration is made on the following basis: <ol style="list-style-type: none"><li>The Directive 93/42/EEC (MDD) certificate(s) covering the listed devices was valid on 26 May 2021.</li><li>The device(s) continue to comply with Directive 93/42/EEC (MDD)</li><li>The device does not undergo a significant change in the design and intended purpose from 26 May 2021.</li><li>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.</li><li>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.</li></ol>

# 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).**

<p>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.</p> <p>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.</p>
Product/Trade Name and Product Code or REF. number: See Appendix A
Device MDR Risk Class: Class IIb

Authorised Signatory:	
Name and Title:	Cristiano Salvadeo
Function	General Mgr, Plant
Place of Issue:	Medolla
Date of Issue:	17-May-2024
Signature:	 <small>Electronically signed by: Cristiano Salvadeo Reason: I approve this document Date: May 17, 2024 11:07 GMT+2</small>

# **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 A: List of medical devices from MDD DoC or PCL**

<b>Product Code or REF number</b>	<b>Product or Trade Name</b>
955680	ARTIS 230V PHYSIO PLUS
955681	ARTIS 230V PHYSIO PLUS LP
955683	ARTIS AFBK PHYSIO PLUS
955682	ARTIS 115V PHYSIO PLUS
115965	ARTIS 115V PHYSIO II
955396	Artis CN

# 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 <sup>2</sup> of the MDD device please include the word "substitute")	MDR Product or Trade Name	MDR Notified Body	MDR Legal Manufacturer
955680	ARTIS 230V PHYSIO PLUS	955990	ARTIS 230V PHYSIO PLUS	<b>TUV</b>	Vantive Health GmbH
955681	ARTIS 230V PHYSIO PLUS LP	955991	ARTIS 230V PHYSIO PLUS LP	<b>TUV</b>	Vantive Health GmbH
955683	ARTIS AFBK PHYSIO PLUS	955993	ARTIS AFBK PHYSIO PLUS	<b>TUV</b>	Vantive Health GmbH
955682	ARTIS 115V PHYSIO PLUS	955990 (substitute)	ARTIS 230V PHYSIO PLUS	<b>TUV</b>	Vantive Health GmbH
115965	Artis 115V Physio II	955990 (substitute)	ARTIS 230V PHYSIO PLUS	<b>TUV</b>	Vantive Health GmbH
955396	Artis CN	955990 (substitute)	ARTIS 230V PHYSIO PLUS	<b>TUV</b>	Vantive Health GmbH

<sup>2</sup> Refers to procedure GQP-09-27 for a definition of substitute device



# EC Certificate - Full Quality Assurance System

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

**No.****CE 00393**

Issued To:

**Gambro Dialysatoren GmbH  
Holger-Crafoord-Strasse 26  
72379 Hechingen  
Germany**

In respect of:

**The design, development and manufacture of sterile single-use hollow fiber dialyzers, apheresis system filters, haemoperfusion system absorption columns and microbial water purification filters**

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: **1994-12-09**Date: **2021-02-01**Expiry Date: **2024-05-26**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance System

## Supplementary Information to CE 00393

Issued To:

**Gambro Dialysatoren GmbH**  
**Holger-Crafoord-Strasse 26**  
**72379 Hechingen**  
**Germany**

Number	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
<b>GMDN Code</b>		
47072	Hollow-fibre haemodialysis dialyser, single-use	A filter used in a haemodialysis system to remove impurities/fluid from the blood of a patient.
36194	Apheresis system filter, whole blood	A sterile device designed to separate plasma from the cellular components of whole blood during automated apheresis therapy.
34422	Haemoperfusion system absorption column	A sterile container that is a component of a haemoperfusion system used for the removal of toxins from a patient's blood, and the holds materials (e.g., activated carbon or resins) which absorb (adsorb) a specific toxin or range of toxins.
58087	Microbial water purification filter	A filter designed to remove general bacteria and other suspended particles from flowing water by creating a mechanical barrier to elements larger than 0.2 micrometers.

First Issued: **1994-12-09**

Date: **2021-02-01**

Expiry Date: **2024-05-26**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# 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 00393**  
Date: **2021-02-01**  
Issued To: **Gambro Dialysatoren GmbH**  
**Holger-Crafoord-Strasse 26**  
**72379 Hechingen**  
**Germany**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Gambro Industries 7 Avenue Lionel Terray BP126 69883 Meyzieu Cedex France	<b>Control of Sterilization Manufacture</b>
Gambro Renal Product Inc. 1101 Jeter Avenue Opelika AL 36801 USA	<b>Control of Sterilization Manufacture</b>
Sterigenics Germany GmbH Kasteler Strasse 45 Wiesbaden 65203 Germany	<b>ETO Sterilization</b>

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# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 00393**  
 Date: **2021-02-01**  
 Issued To: **Gambro Dialysatoren GmbH**  
**Holger-Crafoord-Strasse 26**  
**72379 Hechingen**  
**Germany**

Date	Reference Number	Action
09 December 1994		Original issue.
23 March 1999		Change to scope.
27 November 2001		Change of postal address. Addition of expiry date of 5 years.
09 May 2003		Reissue in new format.
29 September 2004		Change of company name certificate.
20 November 2006		5 year certificate renewal and change of subcontractor name from "IBA Sterilisation & Ionisation" to "Sterigenics Germany GmbH".
11 April 2007		Addition of BBF Sterilisationservice GmbH as a subcontractor for Gamma Sterilization.
20 December 2007		Addition of dialysis concentrates and haemoperfusion cartridges to certificate scope and addition of MTN Neubrandenburg to significant list of subcontractor as design, develop and manufacturing activities.
18 November 2011	7650444	Certificate renewal and addition of Gambro Industries France as a significant subcontractor.

# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 00393**  
 Date: **2021-02-01**  
 Issued To: **Gambro Dialysatoren GmbH**  
**Holger-Crafoord-Strasse 26**  
**72379 Hechingen**  
**Germany**

Date	Reference Number	Action
16 November 2016	8588269	Certificate renewal. Removal of subcontractor MTN Neubrandenburg GmbH.
19 April 2017	8718422	Removal of subcontractor BBF Sterilisationsservice GmbH.
10 July 2018	8890457	Addition of subcontractor Baxter Deutschland GmbH, Edisonstr. 4, Unterschleißheim, 85716, Germany for Regulatory Compliance.
08 March 2019	7780157	Traceable to NB 0086.
24 September 2020	3095588	Removed subcontractor Baxter Deutschland GmbH, Edisonstr. 4, Unterschleißheim, 85716, Germany for Regulatory Compliance. Changed Sterigenics address. Addition of supplementary information table. Removal of dialysis concentrates from the scope. Certificate Renewal.
Current	3334382	Added subcontractor Gambro Renal Product Inc. 1101 Jeter Avenue, Opelika AL 36801 USA.

# 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 Dialysatoren GmbH

Legal Manufacturer Address: Holger-Crafoord-Strasse 26, 72379 Hechingen, Germany

Legal Manufacturer Single Registration Number (SRN): DE-MF-000007011

Authorised Representative Name (if applicable): Not Applicable

Authorised Representative Address: Not Applicable

Authorised Representative Single Registration Number (SRN): Not Applicable

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 00393, issued 2021-02-01

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 <sup>1</sup>: 2028-12-31

<sup>1</sup> 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.
8. Before the original date of expiry as indicated on the MDD Certificate, a signed written agreement 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.
9. A national competent authority has granted a derogation in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure

Product/Trade Name and Product Code or REF. number: See appendix A

Device MDR Risk Class: Class IIa and Class IIb

Authorised Signatory:	
Name and Title:	Verena Kieferle Director Regulatory Affairs Email: <a href="mailto:verena_kieferle@baxter.com">verena_kieferle@baxter.com</a>
Function	PRRC
Place of Issue:	Hechingen
Date of Issue:	12-Feb-2024
Signature:	 <i>Electronically signed by: Verena Kieferle Reason: I approve this document Date: Feb 12, 2024 18:53 GMT</i>

**Gambro Dialysatoren GmbH**  
Holger-Crafoord-Strasse 26  
72379 Hechingen  
Germany

# **Legal Manufacturer's Declaration**

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

<b>Product Code or REF number</b>	<b>Product or Trade Name</b>
114745	Revaclear 300
114746	Revaclear 400
955543	Revaclear 500
114748	Revaclear 300 APAC
114749	Revaclear 400 APAC
115578	Theranova 400
115579	Theranova 500
955365	Theranova 400 EEUR-LATAM
955366	Theranova 500 EEUR-LATAM
955367	Theranova 400 APAC
955368	Theranova 500 APAC
115578C	Theranova 400 China
115579C	Theranova 500 China
102057	Polyflux 14L
102058	Polyflux 17L
104176	Polyflux 21L
109651	Polyflux 14L APAC
109650	Polyflux 17L APAC
112464	Polyflux 21L APAC

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103530	Polyflux 140H
103579	Polyflux 170H
103580	Polyflux 210H
115821	Polyflux 210H
112465	Polyflux 140H APAC
112466	Polyflux 170H APAC
112467	Polyflux 210H APAC
103403	Polyflux 6H
112468	Polyflux 2H
955825	U9000 Plus
955826	U9000 Plus APAC
113092	Theralite 2100
114912	Theralite 2100 APAC

# Legal Manufacturer's Declaration

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## 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 <sup>2</sup> of the MDD device please include the word "substitute")	MDR Product or Trade Name	MDR Notified Body	MDR Legal Manufacturer
114745	Revaclear 300	114745A	Revaclear 300	TÜV	Vantive Health GmbH
114746	Revaclear 400	114746A	Revaclear 400	TÜV	Vantive Health GmbH
955543	Revaclear 500	955543A	Revaclear 500	TÜV	Vantive Health GmbH
114748	Revaclear 300 APAC	114748A	Revaclear 300 APAC	TÜV	Vantive Health GmbH
114749	Revaclear 400 APAC	114749A	Revaclear 400 APAC	TÜV	Vantive Health GmbH
115578	Theranova 400	115578A	Theranova 400	TÜV	Vantive Health GmbH
955365	Theranova 400 EEUR-LATAM				
115579	Theranova 500	115579A	Theranova 500	TÜV	Vantive Health GmbH
955366	Theranova 500 EEUR-LATAM				
955367	Theranova 400 APAC	955367A	Theranova 400 APAC	TÜV	Vantive Health GmbH
955368	Theranova 500 APAC	955368A	Theranova 500 APAC	TÜV	Vantive Health GmbH
115578C	Theranova 400 China	115578C	Theranova 400 China	TÜV	Vantive Health GmbH
115579C	Theranova 500 China	115579C	Theranova 500 China	TÜV	Vantive Health GmbH

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102057	Polyflux 14L	102057A	Polyflux 14L	TÜV	Vantive Health GmbH
102058	Polyflux 17L	102058A	Polyflux 17L	TÜV	Vantive Health GmbH
104176	Polyflux 21L	104176A	Polyflux 21L	TÜV	Vantive Health GmbH
109651	Polyflux 14L APAC	109651A	Polyflux 14L APAC	TÜV	Vantive Health GmbH
109650	Polyflux 17L APAC	109650A	Polyflux 17L APAC	TÜV	Vantive Health GmbH
112464	Polyflux 21L APAC	112464A	Polyflux 21L APAC	TÜV	Vantive Health GmbH
103530	Polyflux 140H	103530A	Polyflux 140H	TÜV	Vantive Health GmbH
103579	Polyflux 170H	103579A	Polyflux 170H	TÜV	Vantive Health GmbH
103580	Polyflux 210H	103580A	Polyflux 210H	TÜV	Vantive Health GmbH
115821	Polyflux 210H	115821A	Polyflux 210H	TÜV	Vantive Health GmbH
112465	Polyflux 140H APAC	112465A	Polyflux 140H APAC	TÜV	Vantive Health GmbH
112466	Polyflux 170H APAC	112466A	Polyflux 170H APAC	TÜV	Vantive Health GmbH
112467	Polyflux 210H APAC	112467A	Polyflux 210H APAC	TÜV	Vantive Health GmbH
103403	Polyflux 6H	103403A	Polyflux 6H	TÜV	Vantive Health GmbH
112468	Polyflux 2H	112468A	Polyflux 2H	TÜV	Vantive Health GmbH
955825	U9000 Plus	955825A	U9000 Plus	TÜV	Vantive Health GmbH

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955826	U9000 Plus APAC	955826A	U9000 Plus APAC	TÜV	Vantive Health GmbH
113092	Theralite 2100	113092A	Theralite 2100	TÜV	Vantive Health GmbH
114912	Theralite 2100 APAC	114912A	Theralite 2100 APAC	TÜV	Vantive Health GmbH

<sup>2</sup> Refers to procedure GQP-09-27 for a definition of substitute device