

## 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 Industries SAS  
Legal Manufacturer Address: 7, avenue Lionel Terray, BP 126, 69883 Meyzieu Cedex, France  
Legal Manufacturer Single Registration Number (SRN): FR-MF-000017812

Authorised Representative Name (if applicable): N/A  
Authorised Representative Address: N/A  
Authorised Representative Single Registration Number (SRN): N/A

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 93142 (issued on 2023-06-14)  
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.

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- |  |
|--|
| <p>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.</p> <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: Refer to Appendix A

Device MDR Risk Class: Class IIb

<b>Authorised Signatory:</b>	
<b>Name and Title:</b>	Pascal Pollet Director, Quality E-mail: pascal_pollet@baxter.com
<b>Function</b>	PRRC
<b>Place of Issue:</b>	Meyzieu, France
<b>Date of Issue:</b>	15 NOVEMBER 2023
<b>Signature:</b>	

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

Product Code or REF number	Product or Trade Name
106696	Prismaflex M60 Set
115305	Prismaflex M60 Set (CKT)
955594	Prismaflex M60 Set (C)
106697	Prismaflex M100 Set
115306	Prismaflex M100 Set (CKT)
955595	Prismaflex M100 Set (C)
109990	Prismaflex M150 Set
115307	Prismaflex M150 Set (CKT)
955467	Prismaflex M150 Set (C)
107643	Prismaflex ST60 Set
115308	Prismaflex ST60 Set (CKT)
107636	Prismaflex ST100 Set
115309	Prismaflex ST100 Set (CKT)
955468	Prismaflex ST100 Set (C)
107640	Prismaflex ST150 Set
115310	Prismaflex ST150 Set (CKT)
955596	Prismaflex ST150 Set (C)
109841	Prismaflex HF20 Set
115313	Prismaflex HF20 Set (CKT)
107140	Prismaflex HF1000 Set
115311	Prismaflex HF1000 Set (CKT)
107142	Prismaflex HF1400 Set
115312	Prismaflex HF1400 Set (CKT)

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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
106696	Prismaflex M60 Set	106696MDR	Prismaflex M60 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
115305	Prismaflex M60 Set (CKT)	115305MDR	Prismaflex M60 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
955594	Prismaflex M60 Set (C)	955594MDR	Prismaflex M60 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
106697	Prismaflex M100 Set	106697MDR	Prismaflex M100 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
115306	Prismaflex M100 Set (CKT)	115306MDR	Prismaflex M100 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
955595	Prismaflex M100 Set (C)	955595MDR	Prismaflex M100 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
109990	Prismaflex M150 Set	109990MDR	Prismaflex M150 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
115307	Prismaflex M150 Set (CKT)	115307MDR	Prismaflex M150 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
955467	Prismaflex M150 Set (C)	955467MDR	Prismaflex M150 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
107643	Prismaflex ST60 Set	107643MDR	Prismaflex ST60 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
115308	Prismaflex ST60 Set (CKT)	115308MDR	Prismaflex ST60 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
107636	Prismaflex ST100 Set	107636MDR	Prismaflex ST100 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
115309	Prismaflex ST100 Set (CKT)	115309MDR	Prismaflex ST100 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA

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955468	Prismaflex ST100 Set (C)	955468MDR	Prismaflex ST100 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
107640	Prismaflex ST150 Set	107640MDR	Prismaflex ST150 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
115310	Prismaflex ST150 Set (CKT)	115310MDR	Prismaflex ST150 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
955596	Prismaflex ST150 Set (C)	955596MDR	Prismaflex ST150 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
109841	Prismaflex HF20 Set	109841MDR	Prismaflex HF20 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
115313	Prismaflex HF20 Set (CKT)	115313MDR	Prismaflex HF20 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
107140	Prismaflex HF1000 Set	107140MDR	Prismaflex HF1000 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
115311	Prismaflex HF1000 Set (CKT)	115311MDR	Prismaflex HF1000 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
107142	Prismaflex HF1400 Set	107142MDR	Prismaflex HF1400 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA
115312	Prismaflex HF1400 Set (CKT)	115312MDR	Prismaflex HF1400 Set	TÜV Süd Product Service GmbH	Baxter Healthcare SA

<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 93142  
**Issued To:** **Gambro Industries**  
**7, Avenue Lionel Terray**  
**BP 126**  
**69883 Meyzieu Cedex**  
**France**

In respect of:

**Design, development and manufacture of sterile single use haemodialysers, haemofilters, blood lines, re-infusion lines, sets for continuous renal replacement therapy (CRRT), sets and tubing systems for plasmfiltration, extracorporeal circulation of blood to be used with blood purification devices and haemoperfusion, ultrafilters for haemodialysis (HD), haemofiltration (HF) and haemodiafiltration (HDF)**

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: **2005-02-08**

Date: **2020-02-13**

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 93142

Issued To: **Gambro Industries**  
**7, Avenue Lionel Terray**  
**BP 126**  
**69883 Meyzieu Cedex**  
**France**

### Quality Management System Certificates:

Number	Device Name	Intended purpose per IFU
<b>Class III</b>		
---	Oxiris set	See CE 98956
---	Evodial	See CE 521926
<b>Class IIb</b>		
<b>44601</b>	Hemofilter	Single use product for Continuous Renal Replacement Therapy
<b>36194</b>	Apheresis filter	Single use products for Therapeutic Plasma Exchange
<b>47072</b>	Hollow-fiber haemodialysis dialyser, single-use	Single use product for treatment of the chronic renal failures
<b>35072</b>	Intravenous line filter	Single use product designed for retention of bacteria, endotoxins and particles in infusion solutions
<b>Class Is</b>		
MD0102	Intravenous line filter	---

First Issued: **2005-02-08**

Date: **2020-02-13**

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

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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 93142**  
 Date: **2020-02-13**  
 Issued To: **Gambro Industries**  
**7, Avenue Lionel Terray**  
**BP 126**  
**69883 Meyzieu Cedex**  
**France**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Bioiks d.o.o. also trading as Bioprod d.o.o. Stegne 11 Ljubljana 1000 Slovenia	<b>Control of Sterilization                      Manufacture</b>
Gambro Dialysatoren GmbH Holger-Crafoord-Strasse 26 72379 Hechingen Germany	<b>Design                      Manufacture</b>
Gambro Renal Products S.A. de C.V. Boulevard Pacifico No. 10014 Parque Industrial Pacifico Tijuana Baja California CP 22643 Mexico	<b>Control of Sterilization                      Manufacture</b>

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**France**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
IONISOS SAS Parc Dombes Côtière Activités 01120 Dagneux France	<b>Gamma Sterilization</b>
IONISOS SAS Zone Industrielle de l'Aubrée 72300 Sable Sur Sarthe France	<b>Gamma Sterilization</b>
Sterlab 485 avenue de Berlin Allée des Jacarandas Parc d'activités du Plateau de Signes 83870 SIGNES France	<b>ETO Sterilization</b>
Sterylene ZI les montoires 3 rue Gustave Eiffel 45500 Gien France	<b>ETO Sterilization</b>

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# EC Certificate - Full Quality Assurance System

## Certificate History

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Date	Reference Number	Action
08 February 2005		First issue following name change from Hospal Industrie to Gambro Industries. Certificate based on CE 00359, first issued 05 December 1994 to Hospal Industrie, Meyzieu.
29 July 2005		Addition of new products to supplementary information.
03 November 2005		Addition of new products to supplementary information.
23 February 2007		Addition of Prismaflex M150 Set to supplementary information (under Sets for Continuous Renal Replacement Therapy).
06 March 2009	7314715	Removed supplementary information to CE 93142 from certificate and implementation of a new scope ensuring that all devices originally listed in the supplementary information are included. Furthermore some minor changes and the removal of Nipro Corporation in the List of significant Subcontractors.
03 February 2010	7297159	Renewal and addition of IONISOS, Sablé sur Sarthe as a significant subcontractor and change of address for IONISOS in Dagneux into Parc Dombes Cœtière Activités.

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Date	Reference Number	Action
05 March 2013	7961179	The addition of 'sets and tubing systems for Hemoperfusion' to the scope of the certificate. Removal of 'Fistula Needles' and 'Tip Stop' wound dressing from the scope of the certificate. Addition of Sterylene to the list of significant subcontractors and the removal of JMS, Bionic and Plasto from the list of significant subcontractors.
27 September 2013	8034759	The addition of extracorporeal circulation of blood to be used with blood purification devices to the scope of the certificate.
15 November 2013	8074038	Addition of 'blood lines' and 're-infusion lines' to the scope of the certificate and addition of Bioiks d.o.o. as a significant subcontractor for manufacture and control of sterilization. Addition of manufacture as an activity subcontracted to Gambro Dialysatoren GmbH. Addition of Gambro Dasco as a significant subcontractor for manufacture.
10 February 2015	8245409	Certificate renewal. Removal of Gambro Dasco as a significant subcontractor for manufacture.
15 December 2015	8436931	Addition of Gambro Renal Products S.A. de C.V., Mexico as a significant subcontractor for Manufacture.

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Date	Reference Number	Action
18 May 2016	8534947	Addition of STERLAB, Vallauris, France as a significant subcontractor for ETO sterilisation.
24 April 2017	8709413	Addition of subcontractor Steril Verona S.r.l., 37060 Erbè (Verona), Italy for ETO sterilization.
10 July 2018	8890443	Addition of subcontractor Baxter Deutschland GmbH, Edisonstr. 4, Unterschleißheim, 85716, Germany for Regulatory Compliance.
08 March 2019	8271474	Traceable to NB 0086.
21 October 2019	9752671	Removal of STERLAB 2720 Ch. St-Bernard 06224 Vallauris France from the list of significant subcontractors. Removal of Sterile Verona S.r.l. Via S. Giuseppe, 31 Erbe Verona 37060 Italy from the list of significant subcontractors. Addition of STERLAB 485 Avenue de Berlin Signes 83870 France as a significant subcontractor for the activity ETO sterilisation. Extension of the activity for Gambro Renal Products S.A. de C.V subcontractor to include "Control of Sterilisation". Addition of supplementary device table.

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Date	Reference Number	Action
Current	3059238	Certificate renewal. Removal of subcontractor Baxter Deutschland GmbH, Edisonstr. 4, UnterschleiBheim, 85716, Germany for Regulatory Compliance. Correction of address typo for critical subcontractor IONISOS.