



Full Quality Assurance

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, fistula needles, associated devices and TIPSTOP wound dressing

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

Anne Boyd, Managing Director, BSI Product Services

First Issued: **8 Feb 2005**

Date: **3 Nov 2005**

Expiration Date: **7 Feb 2010**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

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.

Supplementary Information to CE 93142

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Sterile Single Use Haemodialysers and Haemofilters (Class IIb)
Arylane H4/H6/H9
Arylane L6
Arylane L9
Arylane M4/M6/M9
Nephral ST200/ST300/ST400/ST500
Filtral 6/12/16/20
Crystal ST2800/ST3400/ST4000
Tria Nephross

Wound Dressings
Tipstop Wound Dressings with Alginate (Class IIb)

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Sets For Continuous Renal Replacement Therapy (Class IIb)
Prisma TPE 2000 Set
Prisma M10 Pre Set
Prisma M60 Set
Prisma M60 Pre Set
Prisma M60 Pre-Pump Infusion Set
Prisma M100 Set
Prisma M100 Pre Set
Prisma M100 Pre-Pump Infusion Set
Prisma HF1000 Set
Prisma HF1000 Pre Set
Prisma ST60 Pre Set
Prisma ST100 Pre Set
Prisma ST60 Post Set
Prisma ST100 Post Set

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Sets For Continuous Renal Replacement Therapy (Class IIb) (continued)
Miniflow 10
Multiflow 60/100
Multiflow Kit 60S
Multiflow 60 Kit A0
Multiflow 60 Kit B22
Multiflow 60 Kit B32
Multiflow 100 Kit A0
Multiflow 100 Kit B22
Multiflow 100 Kit B32

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Sets For Continuous Renal Replacement Therapy (Class IIb) (continued)
Prismaflex M60 Set
Prismaflex M100 Set
Prismaflex HF1000 Set
Prismaflex HF1400 Set
Prismaflex ST60 Set
Prismaflex ST100 Set
Prismaflex ST150 Set
Prismaflex TPE1000 set
Prismaflex TPE2000 set

Fistula Needles (Class IIa)
Plume SP
Plume S

Sterile Single Use Ultrafilter (Class IIb)
Ultrasteriset

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