

Certificate

Full Quality Assurance

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

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

A handwritten signature in black ink, appearing to be 'G. Fenton', written over a horizontal line.

Gary Fenton, Global Assurance Director

First Issued: 21 Oct 1999

Date: 20 Jul 2012

Expiration Date: 20 Oct 2014

Page: 1 of 1

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.

raising standards worldwide™



List of Significant Subcontractors

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

Certificate No. **CE 52479**
Date: **20 Jul 2012**
Issued to: **Gambro Dasco S.p.A. Medolla Facility**
Medolla (MO)
Italy

Subcontractor	Service(s) supplied
Gambro Czech Republic s.r.o. Kabelikova 1 750 02 Prerov Czech Republic	Assembly Packaging Testing
Bioster SPA Via A.Piva 46025 Poggio Rusco Mantova Italy	ETO Sterilization
Bioster SpA Via Einaudi, 9 24050 Calcinato Bergamo Italy	ETO Sterilization
Bioster SpA Via 1 Maggio Bastia di Rovolon Padova Italy 35030	E beam Sterilization

List of Significant Subcontractors

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

Certificate No. **CE 52479**
Date: **20 Jul 2012**
Issued to: **Gambro Dasco S.p.A. Medolla Facility**
Medolla (MO)
Italy

Subcontractor	Service(s) supplied
Bioiks D.O.O. Stegne 11 1000 Ljubljana Slovenia	Assembly Packaging Testing
Steril Verona S.r.l. Via S. Giuseppe, 31 Erbè (Verona) 37060 Italy	ETO Sterilization
Gambro Renal Products S.A. de C.V. Boulevard Pacifico No. 10014 Parque Industrial Pacifico Tijuana Baja California Mexico C.P. 22643	Sterile Manufacture
Gammarad Italia S.P.A. Via Marzabotto 4 Minerbio Bologna 40061 Italy	Gamma Irradiation

List of Significant Subcontractors

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

Certificate No. **CE 52479**
Date: **20 Jul 2012**
Issued to: **Gambro Dasco S.p.A. Medolla Facility**
Medolla (MO)
Italy

Subcontractor	Service(s) supplied
Bioster SPA Via Cá Bertoncina 29 Bergamo Seriate 24068 Italy	E beam Sterilization
MEDISCAN GmbH & Co KG Bad Haller Stasse 34 4550 Kremsmünster Austria	E beam Sterilization Gamma Irradiation