

Certificate

Full Quality Assurance

No. CE 52479

Product Services

Issued to:

Gambro Dasco S.p.A.
Medolla Facility
Via Modenese 66
41036 Medolla (MO)
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 the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):



David Ford, Director, Healthcare and Testing Services

First Issued: 21 Oct 1999

Date: 15 Oct 2009

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.

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Certificate

List of Significant Subcontractors

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

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Date: **15 Oct 2009**
Issued to: **Gambro Dasco S.p.A.**
Medolla Facility
Via Modenese 66
41036 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

E beam Sterilization

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Subcontractor

Service(s) supplied

Bioiks D.O.O.
Stegne 11
1000 Ljubljana
Slovenia

Assembly
Packaging
Testing

Gammarad Italia S.P.A.
Via Marzabotto 4
40061 Minerbio
Bologna
Italy

Gamma Irradiation

Bioster SPA
Via Cá BerToncina 29
Bergamo
24068 Seriate
Italy

E beam Sterilization

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History of Quality Assurance Certificate

Certificate No: CE 52479
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Date	Reference	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, Bergamo 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.
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.'