

Certificate

Full Quality Assurance

No. CE 52479

BSI Healthcare 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.

raising standards worldwide™



Certificate

List of Significant Subcontractors

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

Certificate No. **CE 52479**
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

Certificate

List of Significant Subcontractors

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

Certificate No. **CE 52479**
Date: **15 Oct 2009**
Issued to: **Gambro Dasco S.p.A.**
Medolla Facility
Via Modenese 66
41036 Medolla (MO)
Italy

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

Certificate

History of Quality Assurance Certificate

Certificate No: CE 52479
Issue Date: 15 October 2009
Issued to: Gambro Dasco S.p.A.
Medolla Facility
Via Modenese 66
41036 Medolla (MO)
Italy

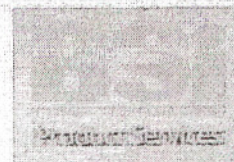
Date	Reference	Action
21 October 1999		First Issue.
14 January 2001		Addition of subcontractor.
05 October 2001		Addition of subcontractor.
22 November 2002		Addition of subcontractor.
02 July 2003		Removal of Bioster subcontractor at Reggilo, Seriate and Caravaggio. The addition of Bioster subcontractor 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.'

raising standards worldwide™



Page 1 of 1

EC Certificate

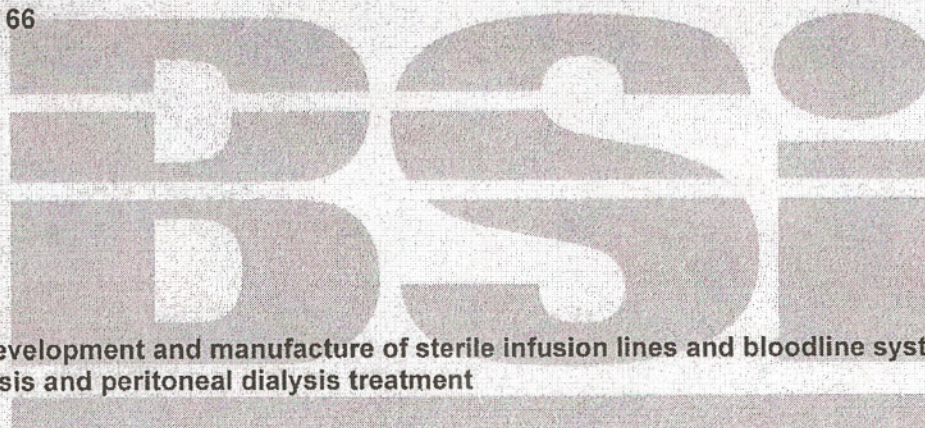


Full Quality Assurance

No. CE 52479

Issued to:

Gambro Dasco S.p.A.
Bloodline Division
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 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):

Alastair Trivett, Managing Director, BSI Product Services – Global

First Issued: 21 Oct 1999

Date: 27 Sep 2006

Expiration Date: 20 Oct 2009

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.

Versta iš anglų kalbos

EB sertifikatas

BSi

Gaminių tarnyba

Visapusės kokybės užtikrinimas

Nr. CE 52479

Kam išduotas:

Gambro Dasco S.p.A.
Bloodline Division [Kraujo magistralių padalinys]
Via Modenese 66
Medolla (MO)
41036
Italija

Objektas:

sterilių infuzijos magistralių ir kraujo magistralių sistemų, naudojamų hemodializės ir peritoninės dializės procedūroms, projektavimas, tobulinimas ir gamyba,

remiantis mūsų patikrinimu, atliktu pagal Tarybos Direktyvos 93/42/EEC II priedo 3.2 dalies reikalavimus.

Už Didžiosios Britanijos standartų institutą (BSI), – notifikuotąją įstaigą pagal anksčiau minėtą Direktyvą (notifikuotosios įstaigos Nr. 0086), – ir BSI vardu:

[Parašas]

Alastair Trivett, Bendrosios BSI gaminių tarnybos direktorius

Pirmą kartą išduotas: **1999 m. spalio 21 d.**

Data: **2006 m. rugsėjo 27 d.**

Galiojimo terminas: **2009 m. spalio 20 d.**

1 psl. iš 1

Patvirtinimo sąlygos

Šis sertifikatas galioja su sąlyga, kad kokybės sistema yra palaikoma pagal Direktyvos reikalavimus. Jei tai nėra specialiai suderinta su BSI, šis patvirtinimas netaikomas jokiems gaminiams, trečiosios šalies suprojektuotiems ir/arba pagamintiems nurodytos šiame sertifikate kompanijos vardu.

BSI gaminių tarnyba

[Institucijos rekvizitus žr. originale]

EC Certificate

List of Significant Subcontractors

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

Certificate No. **CE 52479**
Date: **27 Sep 2006**
Issued to: **Gambro Dasco S.p.A. Bloodline Division**
Medolla (MO)
Italy

Subcontractor	Service(s) supplied
Gambro-Meopta S.R.O. Kabelikova 1/Budova M5 CZ-75058 Prerov Czech Republic	Assembly Packaging Testing
Midial SpA Via Libica 13 91100 Trapani Italy	Assembly Packaging Testing
Gambro Medical Products (Shanghai) Co. Ltd 170 Yuan Yang Road Minhang Economic & Technologic Development Zone Shanghai China 200245	Assembly Packaging Testing
Gambro Dasco SpA Bloodline Division Via Appia KM. 65,934 04013 Latina Scalo Italy	Manufacture

Page: 1 of 2

EB sertifikatas

Svarbiausių subrangovų,

kurie yra pripažinti teikiantys paslaugas, siejamas su gaminiais, kuriems taikomas

Sertifikatas Nr.: CE 52479
Išdavimo data: 2003 m. liepos 02 d.
Išduotas Gambro Dasco S.p.A., Kraujo magistralių padalinys
įmonei: Medolla (MO)
Italija

sąrašas

Subrangovas

Tiekiamos paslaugos

Gambro – Meopta S.R.O.
Kabelikova 1 / Budova M5
CZ-75058 Prerov
Čekijos Respublika

Surinkimas
Pakavimas
Bandymas

Midial SPA
Via Libica 13
91100 Trapani
Italija

Surinkimas
Pakavimas
Bandymas

Gambro Medical Products
(Shanghai) Co. Ltd.
170 Yuan Yang Road
Minang Economic and Technologic
Development Zone
Šanchajus
Kinija
200245

Surinkimas
Pakavimas
Bandymas

Gambro Dasco SPA
Kraujo magistralių padalinys
Via Appia
KM. 65,934
04013 Latina Scalo
Italija

Gamyba

EC Certificate

List of Significant Subcontractors

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

Certificate No. **CE 52479**
Date: **27 Sep 2006**
Issued to: **Gambro Dasco S.p.A. Bloodline Division**
Medolla (MO)
Italy

Subcontractor	Service(s) supplied
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
Bioiks D.O.O. Stegne 11 1000 Ljubljana Slovenia	Assembly Packaging Testing
Bioster SPA Via Cá BerToncina 29 Bergamo 24068 Seriate Italy	E beam Sterilization

Page: 2 of 2

[Institucijos rekvizitus žr. originale]

EB sertifikatas

Svarbiausių subrangovų,

kurie yra pripažinti teikiantys paslaugas, siejamas su gaminiais, kuriems taikomas

Sertifikatas Nr.: CE 52479
Išdavimo data: 2003 m. liepos 02 d.
Išduotas Gambro Dasco S.p.A., Kraujo magistralių padalinys
įmonei: Medolla (MO)
Italija

sąrašas

Subrangovas

Bioster S.p.A.
Via A. Piva
46025 Poggio Rusco
Mantova
Italija

Bioster S.p.A.
Via Einaudi, 9
24050 Calcinato
Bergamo
Italija

Bioster S.p.A.
Via 1 Maggio
Bastia di Rovolon
Padova
Italija

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

Bioster S.p.A.
Via Ca BerNoncina 29
Bergamo
24068 Seriate
Italija

Tiekiamos paslaugos

Sterilizavimas ETO (etilenoksidu)

Sterilizavimas ETO (etilenoksidu)

Sterilizavimas elektronine spinduliuote

Surinkimas
Pakavimas
Bandymas

Sterilizavimas elektronine spinduliuote

2 psl. iš 2

BSI gaminių tarnyba

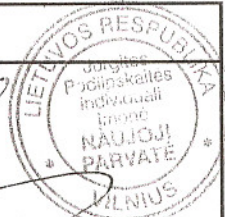
[Institucijos rekvizitus žr. originale]



VERTIMŲ BIURAS "NAUJOJI PARVATĖ"

Vilnius, A. Vivulskio g. 14/8-9, Tel. / faksas 265-10-73

el. paštas: parvate@post.5ci.lt; parvate@takas.lt



Aš, vertėja **MARINA NALIVAIKIENĖ**

patvirtinu, kad šis tekstas yra teisingas ir tikras pridedamojo dokumento vertimas.

Su LR BK 235 str. supažindinta.