



Full Quality Assurance

No. CE 00392

Issued to:

Gambro Lundia AB
Box 10101
Magistratsvagen 16
SE-220 10 Lund
Sweden

In respect of:

The design, development and manufacture of dry and liquid dialysis concentrates and single use dry powder cartridges for dialysis and disinfection.

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, Managing Director, BSI Product Services

First Issued: 9 Dec 1994

Date: 10 Nov 2008

Expiration Date: 3 Nov 2013

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[®]

BSI
Product Services

History of Quality Assurance Certificate

Certificate No: CE 00392
Issue Date: 10 Nov 2008
Issued to: Gambro Lundia AB

| Date | Customer Reference | Action |
|------------------|--------------------|--|
| 09 December 1994 | | First Issue. |
| 04 March 1998 | | Extension to scope. |
| 29 June 2000 | | Removal of sterile disposable PD-lines and catheters from the scope of certification. |
| 11 November 2003 | | Re-issue in new certificate format & certificate renewal. |
| 07 March 2007 | 7017762 | The addition of dry powder concentrates for 'dialysis and disinfection' to the scope of certification. |
| 10 November 2008 | 7292434 | Certificate renewal, the removal of 'Solutions Division' from the company name and the correction of the First Issue date on the history page. |

Versta iš anglų kalbos

EB



SERTIFIKATAS

Sertifikato numeris: CE 00392

Išduotas

GAMBRO LUNDIA AB SOLUTION DIVISION (GLAB SD)
BOX 10101
MAGISTRATSVAGEN 16
S - 220 10 LUND
ŠVEDIJA,

Objektas

sausųjų ir skystųjų dializės koncentratų ir vienkartinio panaudojimo sausųjų miltelių kolonėlių projektavimui, tobulinimui ir gamybai,

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

Už DIDŽIOSIOS BRITANIJOS STANDARTŲ INSTITUCIJĄ (BSI), – registruotą instituciją pagal anksčiau minėtą Direktyvą (institucijos registro Nr. 0086), – ir BSI vardu:

[Parašas]

Anne Boyd, Regioninė direktorė, Produktu tarnyba

Pirmą kartą išduotas: **1994 m. gruodžio 09 d.**

Data: **2003 m. lapkričio 11 d.**

Galiojimo terminas: **2008 m. lapkričio 03 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]

Certificate

List of Significant Sub-contractors

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

Certificate No.: CE 00392

Issue Date: 11 November 2003

Issued to: GAMBRO LUNDIA AB SOLUTIONS DIVISION (GLAB SD).

| Sub-contractor | Service(s) supplied |
|--|--|
| GAMBRO LUNDIA A.B. CENTRE OF EXCELLENCE SOLUTIONS DIVISION EMDALAVAGEN 5 220 10 LUND SWEDEN | Design and Development Activities, Regulatory compliance Support and Central Procurement Services. |

EC



Certificate

Supplementary Information to CE 00392

Issued to: **GAMBRO LUNDIA AB SOLUTION DIVISION (GLAB SD.**

History Page

| Date | Action |
|------------------|---|
| 09 December 1998 | Original issue |
| 04 March 1998 | Extension to scope |
| 29 June 2000 | Removal of sterile disposable PD-lines and catheters from scope |
| 11 November 2003 | Reissue in new format, Five yearly renewal. |

First Issued: 09 December 1994

Date: 11 November 2003

Expiration Date: 03 November 2008

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BSI Product Services

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