

Certificate



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

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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.

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Product Services

Certificate

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.