



## Full Quality Assurance

No. CE 00393

Issued to:

Gambro Dialysatoren GmbH  
Holger-Crafoord-Strasse 26  
72379 Hechingen  
Germany

In respect of:

**the design, development and manufacture of sterile disposable blood purification devices, and ultrafilters for dialysate and infusion solutions**

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: 9 Dec 1994

Date: 20 Nov 2006

Expiration Date: 19 Nov 2011

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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.