

Certificate

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, ultrafilters for dialysate and infusion solutions; dialysis concentrates and haemoperfusion cartridges

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 BSI, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'Rob Wallis'.

Rob Wallis, Chair Certification Body Management Committee

First Issued: 9 Dec 1994

Date: 18 Nov 2011

Expiration Date: 19 Nov 2016

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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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