

Full Quality Assurance

No. CE 01933



Issued to:

**Gambro Dasco SpA
Sondalo Plant
Via Stelvio, 94
IT 23035 Sondalo (SO)
Italy**

In respect of:

The design, development and manufacture of sterile and non-sterile dialysis concentrates and sterile dialysis fluids, dialyzer rinsing solutions and citrate anticoagulant solutions for use in extracorporeal circuits.

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):

A handwritten signature in black ink, appearing to read 'David W. Ford', with a horizontal line underneath.

David W. Ford, Executive Director, Healthcare and Testing Services

First Issued: **29 May 1998**

Date: **5 May 2011**

Expiration Date: **28 May 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.