

Certificate

Design Examination

No. CE 521926



Issued to:

Gambro Industries
7, Avenue Lionel Terray
BP 126
69883 Meyzieu Cedex
France

In respect of:
'EVODIAL' Haemodialyzer/Filter

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

David Ford, Director, Healthcare and Testing Services

First Issued: 25 Feb 2008

Date: 10 Nov 2009

Expiration Date: 24 Feb 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.

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Supplementary Information to CE 521926

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France**

Product: "EVODIAL' Haemodialyzer/Filter

| |
|-------------|
| EVODIAL 1.0 |
| EVODIAL 1.3 |
| EVODIAL 1.6 |
| EVODIAL 2.2 |

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History of Certificate

| Date | BSI Reference Number | Action |
|------------------|----------------------|---|
| 25 February 2008 | 10089012 | First issue |
| 10 November 2009 | 10109867 | Extension of shelf life for EVODIAL Haemodialyzer/Filter to 24 months |

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