

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**

Page: 1 of 3

Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

raising standards worldwide™



Supplementary Information to CE 521926

Issued to:
Gambro Industries

**69883 Meyzieu Cedex
France**

Product: "EVODIAL" Haemodialyzer/Filter

EVODIAL 1.0
EVODIAL 1.3
EVODIAL 1.6
EVODIAL 2.2

First Issued: **25 Feb 2008**
Expiration Date: **24 Feb 2013**

Date: **10 Nov 2009**

Page: 2 of 3

raising standards worldwide™



Supplementary Information to CE 521926

Issued to:
Gambro Industries

69883 Meyzieu Cedex
France

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

First Issued: **25 Feb 2008**

Date: **10 Nov 2009**

Expiration Date: **24 Feb 2013**

Page: 3 of 3

raising standards worldwide™

