

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

Gambro Lundia AB Box 10101 Magistratsvagen 16 SE-220 10 Lund Sweden

Holds Certificate No: MD 503968

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

The design, development, manufacture, warehousing and distribution of: Renal replacement therapy equipment systems including standalone software products, Water treatment systems and extracorporeal blood purification systems, Dry powder cartridges, dialysis fluids, spare parts and cleaning and disinfection of renal therapy equipment

For and on behalf of BSI:

Gary Fenton, Chair, Certification Body Management Committee

First Issued: 04/01/2006

Latest Issue: 20/03/2012

Expiry Date: 01/07/2015



Page: 1 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory

BSI (UK) Headquarters: Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: 0845 080 9000 A Member of the BSI Group of Companies.



Certificate No: MD 503968

Location

18119 Germany **Registered Activities**

| Gambro Lundia AB Box 10101 Magistratsvagen 16 SE-220 10 Lund Sweden | The design, development, manufacture, warehousing and distribution of: Renal replacement therapy equipment systems including standalone software products, Water treatment systems and extracorporeal blood |
|---|---|
| | purification systems, Dry powder cartridges, dialysis fluids, spare parts and cleaning and disinfection of renal therapy equipment |
| Gambro Rostock GmbH Friedrich-Barnewitz-Str.3 Rostock | The design, development and manufacture of extracorporeal blood purification systems. |

First Issued: 04/01/2006

Latest Issue: 20/03/2012

Expiry Date: 01/07/2015

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

BSI (UK) Headquarters: Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: 0845 080 9000 A Member of the BSI Group of Companies.