

MANUFACTURER'S DECLARATION OF CONFORMITY
EUROPEAN COUNCIL DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC
FULL QUALITY ASSURANCE PROCEDURE

Manufacturer : Gambro Dialysatoren GmbH
Business Address : Holger-Crafoord-Strasse 26
72379 Hechingen, Germany
Authorized Representative : Not applicable
Conformity Assessment Procedure : MDD 93/42/EEC, Annex II
Identification of the Notified Body : BSI Notified Body No 0086
Identification of the EC-Certificate : BSI Certificate Nr. 00393
Medical Device(s) : U 9000
Classification : Class IIb
GMDN Code and Term : 58087 Microbial water purification filter, reusable

These devices do not incorporate, as an integral part, a substance as referred to in the Council Directive 93/42/EEC Annex I, Section 7.4.

Identification of a given number of products covered by this declaration : All products manufactured after January 9, 2012

We, the manufacturer, declare that the above mentioned devices comply with the relevant provisions of the European Council Directive 93/42/EEC (as amended by 2007/47/EC).

Place and Date : Hechingen, January 9, 2012
Name of Authorised Signatory / Title : Dr. Michael Hemeke / Plant Manager

Signature : ppa 