

## DECLARATION OF CONFORMITY

**Manufacturer:** Gambro Dialysatoren GmbH  
Holger-Crafoord-Straße 26, 72379 Hechingen

**Authorized Representative:** ( not applicable )

**Conformity Assessment Procedure:** Annex II of the Medical Device Directive 93/42/EEC

**Identification of the Notified Body:** British Standard Institute  
Notified Body Nr. 0086

**Identification of EC-Certificate:** BSI Certificate Nr. 00393 / 09<sup>th</sup> December 1994

**Identification of the device:** U 8000 S

**Classification of the device:** Class II b

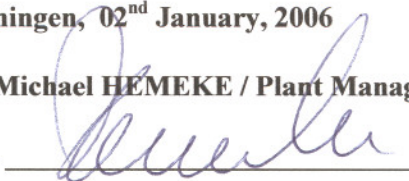
These devices do not incorporate, as an integral part, a substance as referred to in above mentioned Directive, Annex I, Section 7.4

**Identification of a given number of products covered by this declaration:** All products manufactured after 01<sup>st</sup> January 1995

**We, the manufacturer declare that the above devices comply with the relevant provisions of the Council Directive 93/42/EEC**

**Place and date:** Hechingen, 02<sup>nd</sup> January, 2006

**Name / Title:** Dr. Michael HEMEKE / Plant Manager

**Signature:** ppa. 

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**Identification of EC-Certificate:** BSI Certificate Nr. 00393 / 09<sup>th</sup> December 1994

**Identification of the device:** Plasmafilter: PF 1000 N / PF 2000 N

**Classification of the device:** Class II b

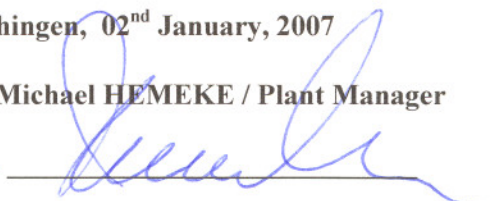
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**Place and date:** Hechingen, 02<sup>nd</sup> January, 2007

**Name / Title:** Dr. Michael HEMEKE / Plant Manager

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**Identification of EC-Certificate:** BSI Certificate Nr. 00393 / 09<sup>th</sup> December 1994

**Identification of the device:** Polyflux 140 H / Polyflux 170 H / Polyflux 210 H

**Classification of the device:** Class II b

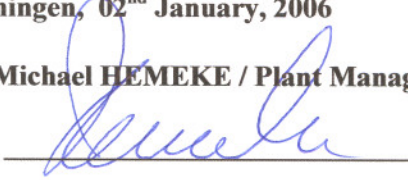
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**Identification of EC-Certificate:** BSI Certificate Nr. 00393 / 09<sup>th</sup> December 1994

**Identification of the device:** Polyflux 14 L / Polyflux 17 L / Polyflux 21 L

**Classification of the device:** Class II b

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**Identification of a given number of products covered by this declaration:** All products manufactured after 01<sup>st</sup> January 1995

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