

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 / 09th December 1994

Identification of the device: U 8000 S

Classification of the device: Class II b

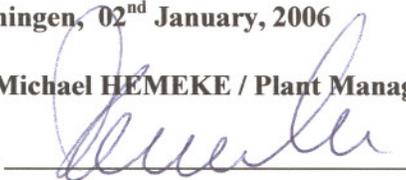
These devices do not incorporate, as an integral part, a substance as referred to in above mentioned Directive, Annex I, Section 7.4

Identification of a given number of products covered by this declaration: All products manufactured after 01st 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, 02nd January, 2006

Name / Title: Dr. Michael HEMEKE / Plant Manager

Signature: ppa. 

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Holger-Crafoord-Straße 26, 72379 Hechingen

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

Identification of EC-Certificate: BSI Certificate Nr. 00393 / 09th December 1994

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

Classification of the device: Class II b

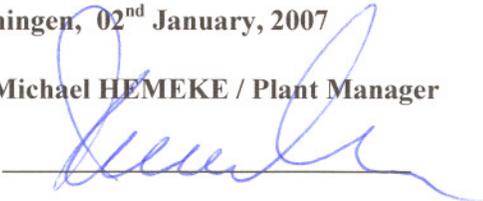
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Identification of the Notified Body: British Standard Institute
Notified Body Nr. 0086

Identification of EC-Certificate: BSI Certificate Nr. 00393 / 09th 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 the Notified Body: British Standard Institute
Notified Body Nr. 0086

Identification of EC-Certificate: BSI Certificate Nr. 00393 / 09th December 1994

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

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 01st January 1995

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

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Name / Title: Dr. Michael HEMEKE / Plant Manager

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