GAMBRO Renal Products

Gambro Dialysatoren GmbH
Holger-Crafoord-Strasse 26
72379 Hechingen
Germany
www.gambro.com

Tel. +49-7471-17-0 (Switchboard)
Fax +49-7471-171157 (Switchboard)

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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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

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

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Place and date:	**Hechingen, 02nd January, 2007**
Name / Title:	**Dr. Michael HEMEKE / Plant Manager**
Signature:	**ppa.** _____

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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:	Polyflux 140 H / Polyflux 170 H / Polyflux 210 H
Classification of the device:	Class II b

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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**

Signature: **ppa.** _____

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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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