

EC Certificate

No.: G1 02 10 24492 214



Decision according to Annex II, Clause 3 of Council Directive 93/42/EEC concerning medical devices.

The Certification Body of TÜV PRODUCT SERVICE certifies that

Fresenius Medical Care AG

61346 Bad Homburg

in the facility(ies)

- **Fresenius Medical Care AG**
Else-Kröner-Str. 1

D-61352 Bad Homburg

for the product(s)/product category(ies)

Medical devices for extracorporeal treatment of blood and peritoneal dialysis
(class IIa and IIb medical devices, for a complete list of product groups see attachment)

maintains a quality system which ensures that the products conform with the essential requirements of the Directive, which apply to them at every stage from design to final controls.

Reasoned assessment see audit report no.: 70031510

Provided the agreed periodical surveillance is carried out, this certificate is valid until October 08, 2007.

Released with the above mentioned certificate number by the Certification Body of TÜV PRODUCT SERVICE.



Department: MHS/ke-o
Date: 2002-10-09

TÜV PRODUCT SERVICE GMBH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.



Attachment to EC Certificate
 No. G1 02 10 24492 214, dated October 9th, 2002
 1st Supplement dated February 2nd 2004
 2nd Supplement dated February 23rd 2005

Non-active medical devices

(AT=Adsorption Treatment / HD=Hemodialysis / PD=Peritoneal Dialysis)

No.	Product group/ product name	Classification in	Rule accordance with 93/42/EEC
1.1	Disinfectants e.g. <i>Diasteril</i> TM , <i>Clearsurfe</i> TM	Ila	15
1.2	Bloodlines and accessories e.g. <i>NaturalLine</i> TM , <i>AdvancedLine</i> TM , <i>BasicLine</i> TM , Filter (Blood return line)	Ila	2
1.3	Tubing systems for AT, HD, PD Plasmapheresis and accessories e.g. <i>Safeline</i> TM , cyclor systems, closure caps, disinfection caps, adaptors, catheters extensions	Ila	2
1.4	Fistula needles and sets	Ila	7
1.5	Catheters for HD	Ila	7
1.6	Dialysis fluid filter e.g. <i>DIASAFE</i> TM , <i>DIASAFE</i> TM plus	Ila	3
1.7	ph electrode for AT	Ila	2
1.8	Solution for conservation	Ila	15
1.9	Fittings and tubes for water treatment systems e.g. distribution ring	Ila	2



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No.	Product group/ product name	Classification in	Rule accordance with 93/42/EEC
2.1	Hemodialysis concentrates e. g. SMARTCART™, bibag [®] , indibag™, sobag™, Flexicart [®] , Granudial [®] , GENIUS [®] -concentrates, Renalyte acid, Renalyte acetate, Renacarb, SKF, BCF, SMARTbag	IIb	3
2.2	Hemodialyser / Hemofilter e. g. HPS-serie, F-serie, FS-serie, HdF-serie, FX-class, Ultraflux [®]	IIb	3
2.3	Plasmafilter e.g. plasmaflux [®] , AlbuFlow	IIb	3
2.4	Catheters for PD and accessories e.g. Tenckhoff catheter, Swan-Neck catheter, silicone glue	IIb	8
2.5	Adsorber e.g. prometh, DALI, PROSORBA, Immunosorba	IIb	3



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Active Medical Devices

(AT=Adsorption Treatment / HD=Hemodialysis / PD=Peritoneal Dialysis)

No.	Product group/ product name	Classification in	Rule accordance with 93/42/EEC
3.1	Heating plates for PD treatment e.g. PD-THERMOSAFE [®] plus	Ila	9
3.2	Bioimpedance device e.g. BCM	Ila	10
3.3	Central delivery systems e.g. CDS08	Ila	11
4.1	Machines for peritoneal dialysis and accessories e.g. sleep safe [™] , PD-night [™]	IIb	11
4.2	Machines for hemodialysis and accessories e.g. 4008 [™] , 5008 [™] , Genius [®]	IIb	11
4.3	Machines for adsorption treatment and accessories e.g. 4008 ADS, ART, Prometheus	IIb	11
4.4	Machines for acute dialysis and extracorporeal blood treatment and accessories e.g. Multifiltrate, ADM 08/ ABM, 4008S ARrT ^{plus}	IIb	11
4.5	Water treatment systems e.g. Aquasafe08, Aquastore08, AquaHWCS, AquaWTU, AquaB, AquaUNO, ROLine 50, AQ and BQ systems, K/RO, K/RO-dual	IIb	11

Munich, CRT-2, 2005-04-20

Reiner Krumme

