

FRESENIUS MEDICAL CARE France

Numéro d'ouverture du Laboratoire : MM 14/317 du 26/06/2014

Nom du Pharmacien Responsable : Madame Solène POURRAT

Numéro d'inscription à l'Ordre National des Pharmaciens : 10002075470

GENERATEUR MONITEUR INDIVIDUEL DE DIALYSE - 5008 S Cordiax

MARQUAGE CE	NOM DU FABRICANT LEGAL	SITE DE FABRICATION
Classe IIb	FRESENIUS MEDICAL CARE Eise Kröner Strasse 1 D - 61348 BAD HOMBURG Allemagne	FRESENIUS MEDICAL CARE Hafenstrasse 9 D-97424 Schweinfurt Allemagne

CARACTERISTIQUES TECHNIQUES

Grâce au système de dialyse 5008 SYSTEM Fresenius propose en standard de nouvelles évolutions thérapeutiques.

Il permet de bénéficier de tous les avantages des modules existants mais également des futurs modules actuellement en validation ou en développement.

GENERATEUR MONITEUR INDIVIDUEL DE DIALYSE - 5008 S Cordiax

La version de base est constituée comme suit :

Une pompe à sang pour biponction
Une pompe pour amorçage physiologique
Un système de détecteur d'air
Système Bibag (système poudre bicarbonate)
Système Diasafe (Filtration du dialysat)
O.C.M. (On Line Clearance Monitor)
Système de mesure de la clairance urée, du calcul du KT/V et du sodium plasmatique
B.T.M. (Blood Temperature Monitor)
Système de mesure instantanée de recirculation à la fistule, mesure du débit de fistule et contrôle de la température corporelle du patient
VAM (Venous Access Monitor)
Système de surveillance du point de ponction
B.P.M. (Blood Pressure Monitor)
Tensiomètre automatique pour prise de pression sanguine artérielle instantanée et programmée
Kit Flush pour rinçage de l'arrivée d'alimentation d'eau osmosée
Une connexion pour distribution centralisée d'acides
Détection de résidus de désinfectants automatique
Minuteur
Ecran couleur LCD RETROECLAIRE tactile 15 pouces TFT avec réduction de la luminosité



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 05 24492 02028

Manufacturer:

Fresenius Medical Care AG & Co. KGaA

61346 Bad Homburg
GERMANY



Product Category(ies):

- Dialysers and Filters for haemodialysis
- Adsorber for therapeutic apheresis
- Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies
- Catheters and Accessories for haemodialysis and peritoneal dialysis
- Fistula needles
- Syringes
- Cleaning and disinfectant agents
- Concentrates and solutions for haemodialysis
- Dialysis fluid supply equipment
- Active medical devices for extracorporeal blood treatment and peritoneal dialysis

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713083654

Valid from:

2016-06-17

Valid until:

2021-06-16



Date, 2016-06-09

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. **G1 16 05 24492 02028**

Facility(ies):

Fresenius Medical Care Deutschland GmbH
St. Wendel Plant
Frankfurter Straße 6 – 8
66606 St. Wendel, GERMANY

Fresenius Medical Care Deutschland GmbH
Schweinfurt Plant
Hafenstraße 9
97424 Schweinfurt, GERMANY

Fresenius Medical Care Deutschland GmbH
Ober-Erlenbach Plant
Steinmühlstraße 24
61352 Bad Homburg / Ober-Erlenbach, GERMANY

Fresenius Medical Care - SMAD
Z.I. de la Pontchonnière
Route de la Chanade / Savigny
69591 L'Arbresle Cedex, FRANCE

Fresenius Medical Care UK Ltd.
Nunn Brook Road, Huthwaite
Sutton-in-Ashfield
Nottinghamshire NG 17 2HU, UNITED KINGDOM

SIS-TER S.p.A.
Via Crema 8
26020 Palazzo Pignano (CR), ITALY

Fresenius Medical Care Espana S.A.
Ctra. Vallderiolf km 0,4
08430 La Roca del Vallès / Barcelona, SPAIN

Novamed GmbH
Free Trade Zone
P.O. Box 35
07070 Antalya, TURKEY

Fresenius Medical Care Srbija d.o.o.
Beogradski put bb
26300 Vršac, SERBIA

Fresenius Medical Care Adsorber Tec GmbH
Magnesitstraße 9
3500 Krems, AUSTRIA



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 05 24492 02443

Manufacturer:

Fresenius Medical Care AG & Co. KGaA

61346 Bad Homburg

GERMANY


**Product
Category(ies):**

- Tubing systems and accessories for haemodialysis, peritoneal dialysis and apheresis therapies
- Rinsing solutions

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

713083654

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Page 1 of 2



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in Class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 16 05 24492 02443

Facility(ies):

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Frankfurter Straße 6 – 8
66606 St. Wendel, GERMANY

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