ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 14 10 62680 097

Manufacturer: **Baxter Healthcare SA**
8010 Zürich
SWITZERLAND

Product Category(ies): **Peritoneal dialysis transfer and cycler sets, protective caps and connection shields; Hemodialysis blood sets**

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.: 713048281-6

Valid from: 2015-01-02
Valid until: 2020-01-01

414424

Date, 2014-12-15

Hans-Heiner Junker

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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(Devices in Class IIa, IIb or III)

No. G1 14 10 62680 097

Facility(ies):

Baxter Healthcare Corporation
1900 North Highway 201, Mountain Home, AR 72653-2497, USA

Baxter Limited
A47, Industrial Estate, MRS3000 Marsa, MALTA

Baxter Healthcare S.A. Singapore Branch
2 Woodlands Industrial Park D, Street 2, (Formerly: 2 Woodlands Industrial Park D, Singapore 738750), Singapore 737778, SINGAPORE

Baxter Healthcare Corporation Medical Products
25212 W. Illinois Route 120, Round Lake, IL 60073, USA

Baxter Healthcare S.A.
Foxford Road, Swinford, Co.Mayo, IRELAND

Bieffe Medital Manufacturing s.a.r.l.
Route de Chebbaou, 2021 Oued Ellil, TUNISIA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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Declaration of Conformity

According to:	**Council Directive 93/42/EEC (MDD)**
Annexes: II, excluding (4)	
Notified Body Certificate(s): G1 14 10 62680 097	
Notified Body's name and address:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany
Notified Body's identification number: 0123	
Manufacturer's name: Baxter Healthcare SA	
Manufacturer's address:	8010 Zürich Switzerland
EC Representative's address: not applicable	
+++We declare under our sole responsibility that the following product(s) conform to the applicable provisions of the above-mentioned Directive:+++	
Product Family/Category:	Peritoneal dialysis transfer and cycler sets, protective caps and connection shields; Hemodialysis blood sets
Code Numbers:	see "CE Marked Product Code List"

+++This declaration is made on the following basis:

- The validity of this document coincides with the expiry date of the corresponding EC Certificate.
- The DOC declares conformity to all product lots released after the issue date, until the expiry of the Certificate.
- Compliance to standards and regulations as defined in the Technical Documentation and Essential Requirements Checklist.+++

Signature: _____ ZURICH 16 DEC 2014

(Steven Martin, VP Quality EMEA) *(Place, Date)*

CE-marked Product Code List
to the Declaration of Conformity

Business: Renal

Certificate Number:	G1 14 10 62680 097
Conformity Assessment Procedure:	Annex II excluding (4)
Classification:	IIa
Sterilisation Method:	ETO and GAMMA for sterile products n.a. for non-sterile products
Facility:	Malta, Mountain Home, Oued Ellil, Singapore, Swinford
Product Category:	Peritoneal dialysis transfer and cycler sets, protective caps and connection shields; Hemodialysis blood sets

Sterile disposables:

PD Transfer Sets:

Code	Description	Date of CE marking	Facility
JMC3437	Acute Set for children CAPD	15. Apr. 2009	Malta
R5C4325	CAPD Solution Transfer Set for use with UV-Flash Germicidal Exchange Device 1.2 m (48")	see CE database	Mountain Home (USA)
R5C4326	CAPD Solution Transfer Set (Short) for use with UV-Flash Germicidal Exchange Device	see CE database	Mountain Home (USA)
R5C4328	CAPD Disposable Disconnect Y-Set for Use with UV-Flash	see CE database	Mountain Home (USA)
R5C4480C	3,65 m Extension Set with Luer-lock Connector	see CE database	Mountain Home (USA)
R5C4482	MiniCap Extended Life PD Transfer Set with Twist Clamp	see CE database	Mountain Home (USA)
R5C4482E	MiniCap Extended Life PD Transfer Set with Twist Clamp	see CE database	Mountain Home (USA)
R5C4483	MiniCap Extended Life PD Transfer Set with Twist Clamp - Extra Short	see CE database	Mountain Home (USA)
R5C4484	MiniCap Extended Life PD Transfer Set with Twist Clamp - Extra Long	see CE database	Mountain Home (USA)

CE-marked Product Code List
to the Declaration of Conformity

Business: Renal

Certificate Number:	G1 14 10 62680 097
Conformity Assessment Procedure:	Annex II excluding (4)
Classification:	IIa
Sterilisation Method:	ETO and GAMMA for sterile products n.a. for non-sterile products
Facility:	Malta, Mountain Home, Oued Ellil, Singapore, Swinford
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PD Cycler Sets:

Code	Description	Date of CE marking	Facility
5C4469C	HomeChoice APD Set with Cassette and 4 Prong Spike	see CE database	Mountain Home (USA)
5C8302C	Low Recirculation Volume APD Set with Cassette (4-Prong Spike)	20. Apr. 2011	Mountain Home (USA)
R5C4427	5-Prong Manifold Set (with Luer Connectors)	see CE database	Mountain Home (USA)
R5C4455	HomeChoice Automated PD Set with Cassette (UV-Flash) and 4-Prong Luers	see CE database	Singapore
R5C4478	HomeChoice Automated PD Set with Cassette and 8-Prong Luers	see CE database	Singapore
R5C4479	HomeChoice Automated PD Set with Cassette and 4-Prong Luers	see CE database	Singapore
R5C4479E	HomeChoice Automated PD Set with Cassette and 4-Prong Luers	see CE database	Singapore
R5C4479T	HomeChoice Automated PD Set with Cassette and 4-Prong Luers	08. Dec.2010	Mountain Home (USA)
R5C4535	HomeChoice APD Set with Cassette (4 Prong Luer with Delta 4 Connector)	see CE database	Mountain Home (USA)
R5C8303	HomeChoice Low Recirculation Volume APD Set with Cassette	see CE database	Singapore

Vivia Blood Set:

Code	Description	Date of CE marking	Facility
5H12101	Vivia Blood Set (BTS)	see CE database	Mountain Home (USA)

CE-marked Product Code List
to the Declaration of Conformity

Business: Renal

Certificate Number:	G1 14 10 62680 097
Conformity Assessment Procedure:	Annex II excluding (4)
Classification:	IIa
Sterilisation Method:	ETO and GAMMA for sterile products n.a. for non-sterile products
Facility:	Malta, Mountain Home, Oued Ellil, Singapore, Swinford
Product Category:	Peritoneal dialysis transfer and cycler sets, protective caps and connection shields; Hemodialysis blood sets

Non-sterile disposables:

PD Ancillary products:

Code	Description	Date of CE marking	Facility
BFPC4211	Connection Shield Sys II with Povidone-Iodine Solution	19. Feb 2010	Swinford (Ireland)
SPC4211	Connection Shield Sys II with Povidone-Iodine Solution	19. Feb 2010	Swinford (Ireland)
BGPC4213	Connection Shield Sys IIK with Povidone-Iodine Solution	19. Feb 2010	Swinford (Ireland)
SPC4213	Connection Shield Sys IIK with Povidone-Iodine Solution	19. Feb 2010	Swinford (Ireland)

PD Protective caps:

Code	Description	Date of CE marking	Facility
1PC4466T	Povidone-Iodine MiniCap	19. Feb 2010	Swinford (Ireland)
BEPC4466	MiniCap with Povidone-Iodine	19. Feb 2010	Swinford (Ireland)
SPC4466	MiniCap with Povidone-Iodine	19. Feb 2010	Swinford (Ireland)
BEPC4486	OptiCap Disconnect Cap with Povidone-Iodine Solution	19. Feb 2010	Swinford (Ireland)
SPC4486	OptiCap Disconnect Cap with Povidone-Iodine Solution	19. Feb 2010	Swinford (Ireland)
SPC4212	Disconnect Cap with Povidone-Iodine Solution	19. Feb 2010	Swinford (Ireland)

This report has been reviewed and verified by: Franziska Walter Date: 16-Dec-2014
(Franziska Walter)

Title: Associate Regulatory Affairs Europe