



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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ZLG-BS-244.10.08



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 062680 0152 Rev. 00**

**Manufacturer:**

**Baxter Healthcare SA**

8010 Zürich  
SWITZERLAND

**Facility(ies):**

**Baxter Healthcare S.A.**

Thurgauerstrasse 130, 8152 Glattpark (Opfikon),  
SWITZERLAND

**Product Category(ies): Plastic Pour Bottles and Bags  
Containing Sterile Fluid  
for Irrigation and Washing**

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.:**

**713162938\_713169128**

**Valid from:**

**2020-01-17**

**Valid until:**


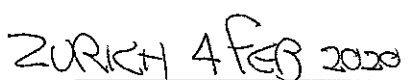
**2024-05-26**

**Date,**

**2020-01-17**

Christoph Dicks  
Head of Certification/Notified Body

# Declaration of Conformity

<b>According to:</b>	<b>Council Directive 93/42/EEC (MDD)</b>
Annexes: II, excluding (4)	
Notified Body Certificate(s): G1 062680 0152 Rev. 00	
Notified Body's name and address: TUV SUD Product Service GmbH Ridlerstrasse 65 80339 Munich, Germany	
Notified Body's identification number: 0123	
Manufacturer's name: Baxter Healthcare SA	
Manufacturer's address: 8010 Zurich 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: Plastic Pour Bottles and bags containing sterile fluid irrigation and washing	
Code Numbers: see "CE Marked Product Code List"	
+++This declaration is made on the following basis: <ul style="list-style-type: none"><li>• The validity of this document shall not start earlier than the validity date of the corresponding EC Certificate.</li><li>• The DOC declares conformity to all product lots released within the above validity period.</li><li>• For Class I non-sterile / non-measuring: self-declaration of conformity.</li><li>• Compliance to standards and regulations as defined in the Technical Documentation and Essential Requirements Checklist.+++</li></ul>	
Signature:	 (Steven Martin, VP Quality EMEA)
	 (Place, Date)

**CE-marked Product Code List  
to the Declaration of Conformity**

**Business: Medical Products**

Certificate Number	G1 062680 0152 Rev. 00
Conformity Assessment Procedure:	Annex II, excluding (4)
Classification:	Ila
Sterilisation Method:	Steam
Facility:	Thetford (UK), Marion (USA), Bieffe (Italy)
Product Category:	Plastic Pour Bottles and bags containing sterile fluid for irrigation and washing

Code	Description	Date of CE marking
14309B7GR	0.9% Sodium Chloride for irrigation, tw 250ml	March 2011
14318B7GR	0.9% Sodium Chloride for irrigation, tw 500ml	March 2011
1A60BD5	Glycine 1,5% std 5000ml	22. June 2011
1A773C2	Sorbitol 5% std 3000ml	22. June 2011
2B7231K	0.9% Sodium Chloride for irrigation in 1000ml sterile container system	see CE Database
3KB7114	Sterile water for irrigation, 1000ml	see CE Database
3KB7117	Sterile water for irrigation, 3000ml	see CE Database
3KB7124	0.9% Sodium Chloride for irrigation, 1000ml	see CE Database
3KB7127	0.9% Sodium Chloride for irrigation, 3000ml	see CE Database
3KB7129	0.9% Sodium Chloride for irrigation, 5000ml	see CE Database
3KB7314	1.5% Glycine for irrigation, 1000ml	see CE Database
3KB7317	1.5% Glycine for irrigation, 3000ml	see CE Database
3KB7319	1.5% Glycine for irrigation, 5000ml	see CE Database
4CCB7306S	Glycine 1% + Mannitol 1% std 3000ml	22. June 2011
4CCB7308S	Glycine 1% + Mannitol 1% std 5000ml	22. June 2011
4CCB7607S	Mannitol + Sorbitol std 3000ml	22. June 2011
4CCB7608S	Mannitol + Sorbitol std 5000ml	22. June 2011
ADCCB2165S	Ringer lactate std 3000ml	22. June 2011
ADCCB7127S	NaCl 0,9% std 3000ml	22. June 2011
ADCCB7129T	NaCl 0,9% std 5000ml	22. June 2011
ADCCB7607T	Mannitol + Sorbitol tw 3000ml	22 June 2011
AECCB7117S	Sterile water for irrigation, 3000ml	see CE Database
AECCB7119S	Sterile water for irrigation, 5000ml	see CE Database
AECCB7127S	0.9% Sodium Chloride for irrigation, 3000ml	see CE Database
AECCB7129S	0.9% Sodium Chloride for irrigation, 5000ml	see CE Database
AECCB7306S	Glycine 1% + Mannitol 1% std 3000ml	22. June 2011
AECCB7308S	Glycine 1% + Mannitol 1% std 5000ml	22. June 2011
AECCB7317S	1.5% Glycine for irrigation, 3000ml	see CE Database
AECCB7317T	1.5% Glycine for irrigation, 3000ml	see CE Database
AECCB7319S	1.5% Glycine for irrigation, 5000ml	see CE Database
AECCB7607S	Mannitol&Sorbitol for irrigation, 3000ml	see CE Database
AECCB7607T	Mannitol&Sorbitol for irrigation, 3000ml	see CE Database
AECCB7608S	Mannitol&Sorbitol for irrigation, 5000ml	see CE Database
AGCCB2166T	Ringer lactate tw 5000ml	22. June 2011
AGCCB7608T	Mannitol + Sorbitol tw 5000ml	22. June 2011
AKB7117	Sterile water for irrigation, 3000ml	see CE Database
AKB7127	0.9% Sodium Chloride for irrigation, 3000ml	see CE Database
AKB7317	1.5% Glycine for irrigation, 3000ml	see CE Database
AKB7927	1.5% Glycine & 1% Ethanol for irrigation, 3000ml	see CE Database
AKF7113	Sterile Water for Irrigation, 500 ml	see CE Database

# CE-marked Product Code List to the Declaration of Conformity

## Business: Medical Products

Certificate Number	G1 062680 0152 Rev. 00
Conformity Assessment Procedure:	Annex II, excluding (4)
Classification:	Ila
Sterilisation Method:	Steam
Facility:	Thetford (UK), Marion (USA), Bieffe (Italy)
Product Category:	Plastic Pour Bottles and bags containing sterile fluid for irrigation and washing

AKF7114	Sterile Water for Irrigation, 1000, ml	see CE Database
Code	Description	Date of CE marking
AKF7123	0.9% Sodium Chloride Irrigation, 500 ml	see CE Database
AKF7124	0.9% Sodium Chloride Irrigation, 1000 ml	see CE Database
AZKF7113	Sterile Water for Irrigation, 500 ml	see CE Database
AZKF7114	Sterile Water for Irrigation, 1000 ml	see CE Database
AZKF7123	0.9% Sodium Chloride Irrigation, 500 ml	see CE Database
AZKF7124	0.9% Sodium Chloride Irrigation, 1000 ml	see CE Database
BLCCB7117S	Water for irrigation std 3000ml	22. June 2011
BLCCB7119S	Water for irrigation std 5000ml	22. June 2011
BLCCB7127S	0.9% Sodium Chloride for irrigation, 3000ml	see CE Database
BLCCB7129S	0.9% Sodium Chloride for irrigation, 5000ml	see CE Database
BLCCB7317S	Glycine 1,5% std 3000ml	22. June 2011
BLCCB7319S	Glycine 1,5% std 5000ml	22. June 2011
BMCCB7117S	Water for irrigation std 3000ml	22. June 2011
BMCCB7119S	Water for irrigation std 5000ml	22. June 2011
BMCCB7127S	0.9% Sodium Chloride for irrigation, 3000ml	see CE Database
BMCCB7129S	0.9% Sodium Chloride for irrigation, 5000ml	March 2010
BMCCB7317S	Glycine 1,5% std 3000ml	22. June 2011
BMCCB7319S	Glycine 1,5% std 5000ml	22. June 2011
DKB7114	Sterile water for irrigation, 1000ml	see CE Database
DKB7117	Sterile water for irrigation, 3000ml	see CE Database
DKB7124	0.9% Sodium Chloride for irrigation, 1000ml	see CE Database
DKB7127	0.9% Sodium Chloride for irrigation, 3000ml	see CE Database
DKB7317	1.5% Glycine for irrigation, 3000 ml	see CE Database
ERKF7113	Sterile Water for Irrigation, 500 ml	18. May 2015
ERKF7114	Sterile Water for Irrigation, 1000 ml	18. May 2015
ERKF7123	0.9% Sodium Chloride for Irrigation, 500 ml	18. May 2015
ERKF7124	0.9% Sodium Chloride for Irrigation, 1000 ml	18. May 2015
FKB7505T	5% Glucose for irrigation, 3000 ml	see CE Database
FKB7515T	Sterile water for irrigation, 1000 ml	see CE Database
FKB7518T	Sterile water for irrigation, 3000 ml	see CE Database
FKB7525T	0.9% Sodium Chloride for irrigation, 1000 ml	see CE Database
FKB7528T	0.9% Sodium Chloride for irrigation, 3000 ml	see CE Database
FKB7535T	1.5% Glycine for irrigation, 1000 ml	see CE Database
FKB7538T	1.5% Glycine for irrigation, 3000 ml	see CE Database
FKB7938T	1.5% Glycine & 1% Ethanol for irrigation, 3000 ml	see CE Database
KKB7114	Sterile water for irrigation, 1000 ml	see CE Database
KKB7117	Sterile water for irrigation, 3000 ml	see CE Database
KKB7124	0.9% Sodium Chloride for irrigation, 1000 ml	see CE Database
KKB7127	0.9% Sodium Chloride for irrigation, 3000 ml	see CE Database
KKB7314	1.5% Glycine for irrigation, 1000 ml	see CE Database

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**Business: Medical Products**

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Classification:	Ila
Sterilisation Method:	Steam
Facility:	Thetford (UK), Marion (USA), Bieffe (Italy)
Product Category:	Plastic Pour Bottles and bags containing sterile fluid for irrigation and washing

Code	Description	Date of CE marking
KKB7317	1.5% Glycine for irrigation, 3000 ml	see CE Database
KKB7920	3% Mannitol & 1% Ethanol for irrigation, 3000 ml	see CE Database
KKF7113	Sterile Water for Irrigation, 500 ml	see CE Database
KKF7114	Sterile Water for Irrigation, 1000 ml	see CE Database
KKF7123	0.9% Sodium Chloride Irrigation, 500 ml	see CE Database
KKF7124	0.9% Sodium Chloride Irrigation, 1000 ml	see CE Database
LKB7518	Sterile water for irrigation, 3000 ml	see CE Database
LKB7528	0.9% Sodium Chloride for irrigation, 3000 ml	see CE Database
LKB7538	1.5% Glycine for irrigation, 3000 ml	see CE Database
LKB7938	1.5% Glycine & 1% Ethanol for irrigation, 3000 ml	see CE Database
MKB7127	0.9% Sodium Chloride for irrigation, 3000 ml	see CE Database
PKB7114	Sterile water for irrigation, 1000 ml	see CE Database
PKB7117	Sterile water for irrigation, 3000 ml	see CE Database
PKB7127	0.9% Sodium Chloride for irrigation, 3000 ml	see CE Database
PKB7317	1.5% Glycine for irrigation, 3000 ml	see CE Database
TKF7113	Sterile Water for Irrigation, 500 ml	see CE Database
TKF7114	Sterile Water for Irrigation, 1000 ml	see CE Database
TKF7123	0.9% Sodium Chloride Irrigation, 500 ml	see CE Database
TKF7124	0.9% Sodium Chloride Irrigation, 1000 ml	see CE Database
UKF7113	STERILE WATER FOR IRRIGATION, 500 ml	see CE Database
UKF7114	STERILE WATER FOR IRRIGATION, 1000 ml	see CE Database
UKF7123	0.9% SODIUM CHLORIDE FOR IRRIGATION, 500 ml	see CE Database
UKF7124	0.9% SODIUM CHLORIDE FOR IRRIGATION, 1000 ml	see CE Database
UKF7164	RINGER SOLUTION FOR IRRIGATION 1000 ml	see CE Database
WKB6371	5% Glucose for irrigation, 3000 ml	see CE Database
WKB6372	2.1% Glycine for irrigation, 3000 ml	see CE Database
WKB7114	Sterile water for irrigation, 1000 ml	see CE Database
WKB7124	0.9% Sodium Chloride for irrigation, 1000 ml	01 April 2010
WKB7127	0.9% Sodium Chloride for irrigation, 3000 ml	see CE Database
WKB7317	1.5% Glycine for irrigation, 3000 ml	see CE Database
3PB7127	0.9% Sodium Chloride for irrigation, 3000ml	see CE Database
PPB7127	0.9% Sodium Chloride for irrigation, 3000ml	see CE Database

This report has been reviewed and verified by:

*Donna Haraden*  
(Donna Haraden)

Date:

*4 Feb 2020*

Title: Director, Regulatory Affairs