

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Legal Manufacturer Name: Baxter Healthcare SA

Legal Manufacturer Address: Thurgauerstrasse 130, 8152 Glattpark (Opfikon), Switzerland

Legal Manufacturer Single Registration Number (SRN): CH-MF-000026124

Authorised Representative Name (if applicable): Baxter Deutschland GmbH

Authorised Representative Address: Edisonstrasse 4, 85716 Unterschleissheim, Germany

Authorised Representative Single Registration Number (SRN): DE-AR-000010308

Notified Body Name and Address: TUV SUD Product Service GmbH, Ridlerstrasse 65, 80339, Munich, Germany

Notified Body Identification Number: 0123

MDD Certificate Number: G1 062680 0152 Rev. 00

Original expiry date as indicated on the MDD Certificate prior to the extension of the validity:
26-May-2024

End date of extended validity/transition period ¹: 31-December-2028

¹ according to Article 120 3a, as amended by Regulation (EU) 2023/607 (MDR).

+++ We, as the legal manufacturer declare under our sole responsibility:

- for the above listed **MDD Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*
- the listed **device(s)** and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions: +++

This declaration is made on the following basis:

1. The Directive 93/42/EEC (MDD) certificate(s) covering the listed devices was valid on 26 May 2021.
2. The device(s) continue to comply with Directive 93/42/EEC (MDD)
3. The device does not undergo a significant change in the design and intended purpose from 26 May 2021.
4. The device(s) do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

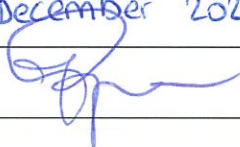
NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

5. Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.
6. A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) is put in place by the manufacturer no later than 26 May 2024.
7. A formal application in accordance with Section 4.3, first subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made to the notified body for the device(s) listed on this declaration or has been made in respect of a device intended to substitute a device listed on this declaration, no later than 26 May 2024 and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII, Regulation (EU) 2017/745 (MDR) no later than 26 September 2024.

Product/Trade Name and Product Code or REF. number: Refer to Appendix A

Device MDR Risk Class: IIb

Authorised Signatory:

Name and Title:	Fabrizio Pasqua, Head of RA/QA
Function	QMR
Place of Issue:	Opfikon
Date of Issue:	13 December 2023
Signature:	

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Appendix A: List of medical devices from MDD DoC or PCL

Product Code or REF number	Product or Trade Name
AZKF7113	STERILE WATER FOR IRRIGATION, 500ml
AKF7113	STERILE WATER FOR IRRIGATION, 500 ml
ERKF7113	Sterile Water for Irrigation, 500 ml
KKF7113	STERILE WATER FOR IRRIGATION, 500 ml
TKF7113	STERILE WATER FOR IRRIGATION, 500 ml
UKF7113	STERILE WATER FOR IRRIGATION, 500 ml
AKF7114	STERILE WATER FOR IRRIGATION, 1000 ml
AZKF7114	STERILE WATER FOR IRRIGATION, 1000 ml
ERKF7114	Sterile Water for Irrigation, 1000 ml
KKF7114	STERILE WATER FOR IRRIGATION, 1000 ml
TKF7114	STERILE WATER FOR IRRIGATION, 1000 ml
UKF7114	STERILE WATER FOR IRRIGATION, 1000 ml
AKF7123	0.9% SODIUM CHLORIDE IRRIGATION, 500 ml
AZKF7123	0.9% SODIUM CHLORIDE IRRIGATION, 500 ml
KKF7123	0.9% SODIUM CHLORIDE IRRIGATION, 500 ml
TKF7123	0.9% SODIUM CHLORIDE IRRIGATION, 500 ml
AKF7124	0.9% SODIUM CHLORIDE IRRIGATION, 1000 ml
AZKF7124	0.9% SODIUM CHLORIDE IRRIGATION, 1000 ml
KKF7124	0.9% SODIUM CHLORIDE IRRIGATION, 1000 ml

PARENT DOCUMENT(S): **GQP-09-27**
(current rev.)

Page 3 of 7

PUBLIC RELEASE

FORM NO.: **GQT-09-27-02**
 REVISION: **A**
 ISSUE DATE: **SEE STAMP**
 EFFECTIVE DATE: **SEE STAMP**

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

TKF7124	0.9% SODIUM CHLORIDE IRRIGATION, 1000 ml
ERKF7123	0.9% Sodium Chloride for Irrigation, 500 ml
UKF7123	0.9% SODIUM CHLORIDE FOR IRRIGATION, 500 ml
ERKF7124	0.9% Sodium Chloride for Irrigation, 1000 ml
UKF7124	0.9% SODIUM CHLORIDE FOR IRRIGATION, 1000 ml
3KB7117	Sterile Water for Irrigation, 3000ml
AKB7117	Sterile Water for Irrigation, 3000ml
DKB7117	Sterile Water for Irrigation, 3000ml
FKB7518T	Sterile water for Irrigation, 3000 ml
KKB7117	Sterile Water for Irrigation, 3000 ml
PKB7117	Sterile Water for Irrigation, 3000 ml
3KB7114	Sterile Water for Irrigation, 1000ml
DKB7114	Sterile Water for Irrigation, 1000ml
FKB7515T	Sterile water for Irrigation, 1000 ml
KKB7114	Sterile Water for Irrigation, 1000 ml
PKB7114	Sterile Water for Irrigation, 1000 ml
WKB7114	Sterile water for Irrigation, 1000 ml
3KB7127	0.9% Sodium Chloride for Irrigation, 3000ml
AKB7127	0.9% Sodium Chloride for Irrigation, 3000ml
DKB7127	0.9% Sodium Chloride for Irrigation, 3000ml
FKB7528T	0.9% Sodium Chloride for Irrigation, 3000 ml
KKB7127	0.9% Sodium Chloride for Irrigation, 3000 ml

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

MKB7127	0.9% Sodium Chloride for Irrigation, 3000 ml
PKB7127	0.9% Sodium Chloride for Irrigation, 3000 ml
WKB7127	0.9% Sodium Chloride for Irrigation, 3000 ml
3KB7124	0.9% Sodium Chloride for Irrigation, 1000ml
DKB7124	0.9% Sodium Chloride for Irrigation, 1000ml
FKB7525T	0.9% Sodium Chloride for Irrigation, 1000 ml
KKB7124	0.9% Sodium Chloride for Irrigation, 1000 ml
WKB7124	0.9% Sodium Chloride for Irrigation, 1000 ml
3KB7317	1.5% Glycine for Irrigation, 3000ml
AKB7317	1.5% Glycine for Irrigation, 3000ml
DKB7317	1.5% Glycine for Irrigation, 3000 ml
KKB7314	1.5% Glycine for Irrigation, 1000 ml
FKB7538T	1.5% Glycine for Irrigation, 3000 ml
KKB7317	1.5% Glycine for Irrigation, 3000 ml
LKB7538	1.5% Glycine for Irrigation, 3000 ml
PKB7317	1.5% Glycine for Irrigation, 3000 ml
WKB7317	1.5% Glycine for Irrigation, 3000 ml
3KB7314	1.5% Glycine for Irrigation, 1000ml
FKB7535T	1.5% Glycine for Irrigation, 1000 ml
WKB6371	5% Glucose for Irrigation, 3000 ml
AECCB7119S	Sterile water for irrigation, 5000ml
AECCB7117S	Sterile water for irrigation, 3000ml

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

BLCCB7119S	Water for Irrigation std 5000ml
BMCCB7119S	Water for Irrigation std 5000ml
BLCCB7117S	Water for Irrigation std 3000ml
BMCCB7117S	Water for Irrigation std 3000ml
ADCCB7127S	0.9% Sodium Chloride for Irrigation, 3000ml
ADCCB7129T	0.9% Sodium Chloride for Irrigation, 5000ml
14318B7GR	0.9% Sodium Chloride for irrigation, tw 500ml
14309B7GR	0.9% Sodium Chloride for irrigation, tw 250ml
AECCB7129S	0.9% Sodium Chloride for irrigation, 5000ml
BLCCB7129S	0.9% Sodium Chloride for Irrigation, 5000ml
BMCCB7129S	0.9% Sodium Chloride for Irrigation, 5000ml
AECCB7127S	0.9% Sodium Chloride for irrigation, 3000ml
BLCCB7127S	0.9% Sodium Chloride for Irrigation, 3000ml
BMCCB7127S	0.9% Sodium Chloride for Irrigation, 3000ml
ADCCB2165S	Ringer lactate std 3000ml
AGCCB2166T	Ringer Lactate tw 5000ml
BMCCB7317S	Glycine 1,5% std 3000ml
BLCCB7317S	Glycine 1,5% std 3000ml
BMCCB7319S	Glycine 1,5% std 5000ml
BLCCB7319S	Glycine 1,5% std 5000ml
AECCB7319S	1.5% Glycine for irrigation, 5000ml
AECCB7317S	1.5% Glycine for irrigation, 3000ml
AECCB7317T	1.5% Glycine for irrigation, 3000ml

PARENT DOCUMENT(S): **GQP-09-27**
(current rev.)

Page 6 of 7

PUBLIC RELEASE

FORM NO.: **GQT-09-27-02**
REVISION: **A**
ISSUE DATE: **SEE STAMP**
EFFECTIVE DATE: **SEE STAMP**

Legal Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and the compliance of the devices and us as their legal manufacturer with the conditions for the continued placing on the market and putting into service.

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

1A60BD5	Glycine 1,5% std 5000ml
---------	-------------------------