

## 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
Authorized Representative Name (if applicable): Baxter Deutschland GmbH Authorized Representative Address: Edisonstrasse 4, 85716 Unterschleissheim, Germany Authorized Representative Single Registration Number (SRN): DE-AR-000010308
Notified Body Name and Address: TUV SUD Notified Body Identification Number: 0123 MDD Certificate Number: G1 062680 0155 Rev. 00 Original expiry date as indicated on the MDD Certificate prior to the extension of the validity: 2024-05-26 End date of extended validity/transition period <sup>1</sup> : 2028-12-31  <sup>1</sup> according to Article 120 3a, as amended by Regulation (EU) 2023/607 (MDR).
+++ We, as the legal manufacturer declare under our sole responsibility: <ul style="list-style-type: none"><li>for the above listed <b>MDD Certificate</b> the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met <i>and/or</i></li><li>the listed <b>device(s)</b> 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,</li></ul> namely by fulfilling the following conditions: +++
This declaration is made on the following basis: <ol style="list-style-type: none"><li>The Directive 93/42/EEC (MDD) certificate(s) covering the listed devices was valid on 26 May 2021.</li><li>The device(s) continue to comply with Directive 93/42/EEC (MDD)</li><li>The device does not undergo a significant change in the design and intended purpose from 26 May 2021.</li><li>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.</li></ol>

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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: See Appendix A
Device MDR Risk Class: IIa

Authorized Signatory:	
Name, Email Address and Title:	Serkan Sezar, <a href="mailto:serkan_sezer@baxter.com">serkan_sezer@baxter.com</a> . Leader, Quality and Regulatory
Function	PRRC
Place of Issue:	Baxter Healthcare SA / Zurich Switzerland
Date of Issue:	25-Jan-2024
Signature:	 <i>Electronically signed by: Serkan Sezer Reason: I approve this document Date: Jan 25, 2024 17:35 GMT+1</i>

## **Legal Manufacturer's Declaration**

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### **Appendix A: List of medical devices that are in compliance with the conditions listed in Article 120.3c**

<b>Product Code or REF number</b>	<b>Product or Trade Name</b>
<b>3400667</b>	<b>Duploject Combi</b>
<b>3400663</b>	<b>Duploject System 10 m</b>
<b>3400662</b>	<b>Duploject System 2 ml/4 ml</b>
<b>1502324</b>	<b>Duplocath Application Catheter 35 M.I.S.</b>
<b>1502323</b>	<b>Duplocath Application Catheter 25</b>
<b>1502325</b>	<b>Duplocath Application Catheter 180</b>
<b>0600021</b>	<b>Coseal Spray Set</b>
<b>1504272</b>	<b>Tisseel / Artiss Spray Set</b>