

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: TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany Notified Body Identification Number: 0123 MDD Certificate Number: Certificate: Full Quality Assurance System: G1 062680 0156 Rev.00 Design-Examination Certificate G7AO 062680 0106 Rev.01 Original expiry date as indicated on the MDD Certificate prior to the extension of the validity: Full Quality Assurance System: 26th May 2024 Design-Examination Certificate: 26th May 2024 End date of extended validity/transition period ¹ : 31 December 2027 ¹ 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">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 <i>and/or</i>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: <ol style="list-style-type: none">The Directive 93/42/EEC (MDD) certificate(s) covering the listed devices was valid on 26 May 2021.The device(s) continue to comply with Directive 93/42/EEC (MDD)

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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.
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.
8. Before the original date of expiry as indicated on the MDD Certificate, a signed written agreement 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.

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

Device MDR Risk Class: Class III

Authorised Signatory:	
Name and Title:	Fabrizio Pasqua VP, Quality • Renal OAM - Quality
Function	QMR
Place of Issue:	Baxter Healthcare Corporation
Date of Issue:	2-Oct-2023
Signature:	 Fabrizio Pasqua (Oct 2, 2023 20:54 GMT+2)

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

Product Code or REF number	Product or Trade Name
1503353	Floseal Hemostatic Matrix, 5 mL (Floseal VH S/D)
1503354	Floseal Hemostatic Matrix, 10 mL (Floseal VH S/D)