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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 037258 0013 Rev. 01

Manufacturer:

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY

SRN Manufacturer - DE-MF-000009273

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapter I is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 037258 0013 Rev. 01

Report No.: 713386446

Preceding Certificate No.: G70 037258 0013 Rev. 00

Valid from: 2026-02-11
Valid until: 2029-01-15

Date of Initial Issuance: 2024-01-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-02-11

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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No. G70 037258 0013 Rev. 01

Classification: Class III
Basic UDI-DI: 081002044BloodProcessDv3W
Intended Purpose: The InterSol solution is a plasma replacement fluid for the preparation and storage of platelet concentrates in routine blood banking conditions until the platelets are transfused to patients requiring such transfusions.
Device(s): InterSol Solution

List of variants for Basic UDI-DI 081002044BloodProcessDv3W - InterSol Solution:

No.	Article number	Article name/description
1	RGB8150	InterSol Solution with Male Luer Lock Connector, 500 mL
2	RGB8128	InterSol Solution, 280 mL
3	RGB8120	InterSol Solution, 200 mL

The validity of this certificate depends on conditions and/or is limited to the following: -/-

Revision History:

Rev.	Dated	Report	Description
00	2024-01-16	713192621	Initial issuance
01	2026-02-11	713386446	Reduced: Device(s)/group of device(s) removed

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