



EU Quality Management System Certificate (MDR)

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

No. G12 037258 0042 Rev. 00

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 established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system 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 conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System 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:G12 037258 0042 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G12_037258_0042_Rev_00)

Report No.: 713318061

Valid from: 2024-03-04

Valid until: 2029-03-03

Christoph Dicks
Head of Certification/Notified Body

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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

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No. G12 037258 0042 Rev. 00

Classification: Class III
Device Group: B99 - HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES - OTHER
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

The validity of this certificate depends on conditions and/or is limited to the following: -none

Revision History:

Rev.	Dated	Report	Description
00	2024-03-04	713318061	Initial issuance