



**EU DECLARATION OF CONFORMITY**

Annex IX, chapter I and III of Regulation 2017/745 according to  
EU certificate No. G11 037258 0015 Rev. 01 and Expiration Date 2027-07-31  
issued by Notified Body TÜV Süd Product Service GmbH,  
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

Total Parenteral Nutrition SIFEVA SIFRAMIX

Refer to attachment  
(Product name)

Refer to attachment  
(article number)

Device classification according to Annex VIII, clause 4.2, rule 2

Class Is

We

**Fresenius Kabi AG, Else-Kröner-Str. 1  
61352 Bad Homburg, Germany**  
Single Registration Number (SRN): DE-MF-000009273

manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of the Medical Device Regulation 2017/745 and any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The products comply with the general safety and performance requirements of Annex I, further applicable standards and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

Bad Hersfeld, 31<sup>st</sup>October 2024

Dr. Sandra Leipold, Senior Manager RA

Signed by:

Signer Name: Sandra Leipold

Signing Reason: I approve this document

Signing Time: 31-Oct-2024 | 3:04 PM CET

Place and date of issue/

Name (printed letters), position and signature of authorized person/

B9645EE7DA3E453B9FA14298C5C5AB

Valid starting with the original date of the document until product change



**Attachment to EU DECLARATION OF CONFORMITY**

**Total Parenteral Nutrition SIFEVA SIFRAMIX**

Article Number	Product Name	Basic UDI-DI
B000686	Sacca in EVA SIFEVA® da 250 ml	42502737NIV51611s000000CB
B000690	Sacca in EVA SIFEVA® da 500 ml	42502737NIV51611s000000CB
B000694	Sacca in EVA SIFEVA® da 1000 ml	42502737NIV51611s000000CB
B000700	Sacca in EVA SIFEVA® da 2000 ml	42502737NIV51611s000000CB
B000712	Sacca in EVA SIFEVA® da 3000 ml	42502737NIV51611s000000CB
B000716	Sacca in EVA SIFEVA® da 3000+500 ml	42502737NIV51611s000000CB
B101190	Sacca in EVA SIFEVA® da 150 ml	42502737NIV51611s000000CB
B101191	Sacca in EVA SIFEVA® da 500+150 ml	42502737NIV51611s000000CB
B101192	Sacca in EVA SIFEVA® da 1200+400 ml	42502737NIV51611s000000CB
B000682	Sacca in EVA SIFEVA® da 250 ml	42502737NIV51611s000000CB
B000687	Sacca in EVA SIFEVA® da 500 ml	42502737NIV51611s000000CB
B000691	Sacca in EVA SIFEVA® da 1000 ml	42502737NIV51611s000000CB
B000696	Sacca in EVA SIFEVA® da 2000 ml	42502737NIV51611s000000CB
B000704	Sacca in EVA SIFEVA® da 3000 ml	42502737NIV51611s000000CB
B000705	Sacca in EVA SIFEVA® da 3000 ml	42502737NIV51611s000000CB
B000709	Sacca in EVA SIFEVA® da 3000 ml	42502737NIV51611s000000CB
B000715	Sacca in EVA SIFEVA® da 3000 + 500 ml	42502737NIV51611s000000CB
B000718	Linea per il modulo nutrienti	42502737NIV51611s000000CB
B000719	Linea lipidi per il modulo nutrienti	42502737NIV51611s000000CB
B000721	Linea per il modulo a 6 elettroliti	42502737NIV51611s000000CB
B000723	Linea per il modulo pediatrico	42502737NIV51611s000000CB
B000724	Linea per il modulo M36	42502737NIV51611s000000CB
B009554	Linea per il modulo a 8 elettroliti	42502737NIV51611s000000CB
B009555	Linea di scarico per il modulo M380	42502737NIV51611s000000CB
B009556	Linea riempimento per il modulo M380	42502737NIV51611s000000CB
B009557	Linea riempimento ad Y per il modulo M380	42502737NIV51611s000000CB

**Certificate Of Completion**

Envelope Id: 729B645E587E4B1E8178944DAC3BA36E	Status: Completed
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