



EC DECLARATION OF CONFORMITY

Annex II excluding (4) of Directive 93/42/EEC
according to EC-certificate No. G1 047402 0083 and Expiration Date 26 May
2024

issued by Notified Body (TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123)

Purisolet SM diluted, solution for irrigation / Purisolet SM verdünnt, Spüllösung

see attachment
(article number)

Class IIa - IIb

We

Fresenius Kabi AG
61346 Bad Homburg, Germany

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 Directive 93/42/EEC, as amended by 2007/47/EC, and its transposition into national laws. The products comply with the essential 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.

Friedberg *29. Juni 2024*

Linda Klee *Linda Klee*

Place and date of issue/

Name (printed letters), position and signature of QA Compliance
Manager, PU Friedberg

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



**Attachment to EC Declaration of
Conformity**

**Purisole SM diluted, solution for
irrigation /
Purisole SM verdünnt, Spüllösung**

Article Code	Description	GMDN
F2577681	Purisole SM diluted, Careflex Duo, 1500ml	37207
F2577161	Purisole SM diluted, Careflex Duo, 3000ml	37207
F2578161	Purisole SM diluted, Careflex Duo, 3000ml	37207
F2579161	Purisole SM diluted, Careflex Duo, 3000ml	37207
F2577201	Purisole SM diluted, Careflex Duo, 5000ml	37207
2560181	Purisole SM diluted, Kabi Container, 10L	37207
2561181	Purisole SM diluted, Kabi Container, 10L	37207