



**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)

**Irrigation Solutions**

**Purisole SM diluted**  
(Product name)

**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 **17 JUN 2020**

Nima Sandoghdar

Place and date of issue/

Name (printed letters), position and signature of Quality Systems & cGMP-Compliance Manager

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



**Attachment to EC Declaration of  
Conformity**

**Purisole SM diluted**

<b>Article Code</b>	<b>Description</b>
2560181	Purisole SM 10L Kabi Container
F2577161	Purisole SM 3000ml CFX DUO
F2577201	Purisole SM CFX DUO 5000ml
F2577681	Purisole SM CFX DUO 1500 ml
F2578161	Purisole SM CFX DUO 3000ml PT