



Sartorius Stedim Biotech GmbH 37070 Goettingen Germany

Contact  
Dr. Christian Hoffmann  
  
Phone +49.551.308.2406  
Fax +49.551.308.3289

christian.hoffmann@  
sartorius.com

10 January 2018

Sartorius  
Stedim Biotech GmbH  
August-Spindler-Straße 11  
37079 Goettingen, Germany

Phone +49.551.308.0  
Fax +49.551.308.3289  
www.sartorius-stedim.com

## Confirmation

### Sartoclear Depth Filter Modules & Sheets for Food & Beverage

The following products

#### Sartoclear Depth Filter Sheets

290C...  
290F...  
290S...

#### Sartoclear Depth Filter Modules

291C...  
291F...  
291S...

Registered Office: Goettingen  
Local Court of Registration:  
Amtsgericht Goettingen  
HRB No. 200266

Managing Directors:  
Uwe Becker,  
Dr. René Fäber

Chairman of the Supervisory Board:  
Dr. Joachim Kreuzburg

distributed by Sartorius Stedim Biotech meet the requirements laid down in the Framework Regulation (EC) No 1935/2004 and Commission Regulation (EU) No 10/2011 of 14th January 2011 on plastic materials and articles intended to come in to contact with food, and subsequent amendment and correction to this regulation:

- Commission Regulation (EU) No 1282/2011 of 28th November 2011
- Commission Regulation (EU) No 1183/2012 of 30th November 2012
- Commission Regulation (EU) No 202/2013 of 3rd March 2013
- Commission Regulation (EU) No 2015/174 of 5th February 2015
- Commission Regulation (EU) No 2016/1416 of 24th August 2016
- Commission Regulation (EU) No 2017/752 of 28th April 2017

The intended use of these products is the industrial filtration of aqueous, acidic and light alcoholic foodstuffs up to 50% (v/v) at a maximum contact temperature of 40 °C.

- the Depth Filter Sheets meet the requirements of recommendation XXXVI/1 of the Federal Institute for Risk Assessment (BFR)
- The silicone gaskets meet the requirements of recommendation XV of the Federal Institute for Risk Assessment (BFR)
- The plastic components meet the requirement of Commission Directive 10/2011/EC + amendments in all examinations points.



2

Migration testings were conducted on Sartoclear depth filter module with the following food simulants according to Commission Directive 10/2011 /EC and supplement:

- Acetic acid 3 Gew.-% (Simulant B): Duration: 24 hat 104 °F (40°C)
- Ethanol, 95-Vol.-% (Simulant O2): Duration: 24 hat 104°F (40°C)
- Vegetable oil/ Isooctan (Simulant O2): Duration: 5 h at 68°F (20°C)

The global migration as well as the specific migrations meet the legal requirements upon proper use. Sartoclear P depth filter module is perfectly suitable for the filtration of foodstuffs.

The information contained in this Statement represents the current information status and is given in good faith pursuant to information available from our supplier.

Sincerely  
Sartorius Stedim Biotech GmbH  
Site Manager QA Filtration Products

Dr. Hartmut Hennig

Global Regulatory Affairs Coordinator

Dr. Christian Hoffmann