

Sartorius Stedim Biotech GmbH, 37079 Goettingen, Germany

To whom it may concern

21. September 2020

Shelf life statement for the Sartorius process filter portfolio

Dear valued customer,

This statement informs about the shelf life of the Sartorius process filter portfolio.

1. Shelf life of Sartorius process filter portfolio

In order to determine the shelf life of Sartorius process filters, Sartorius has decided to perform a real life study. A comprehensive test program was performed according to Sartorius internal working instructions.

In order to continuously verify the obtained data and thereby confirm the assigned shelf lives, a continuous test program was established. For this purpose, the program was integrated into the Sartorius standard operating procedure "Jahresprüfplan".

An annual review of the regular test program is scheduled to review its currentness and incorporate new product families into the sampling plan.

The sampling plan specifies the type and number of process filters, which have to be taken from the Sartorius standard production in specified time periods and then undergo the respective testing.

Conclusions and Decisions:

Shelf lives under recommended storage conditions mentioned in chapter 3.

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|-----|--|---------|
| 1.1 | All non-sterile standard process filter
Cartridges, Mini Cartridges, Capsules, MidiCaps® and MaxiCaps® /
T-Style MaxiCaps® (except Sartolon) | 5 years |
| 1.2 | Sartolon standard filter devices | 3 years |
| 1.3 | Sterile delivered (autoclaved) standard process filter
Capsules, MidiCaps® and MaxiCaps® / T-Style MaxiCaps® | 3 years |
| 1.4 | Sartobind®
Sartobind® Q and S | 5 years |

Sartorius Stedim Biotech GmbH
Phone +49 551 308 0
Fax +49 551 308 3289
www.sartorius-stedim.com

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

Managing Directors:
Uwe Becker,
Bettina Berendsen

Chairman of the Supervisory Board:
Dr. Joachim Kreuzburg

Sartobind® STIC PA	3 years
Sartobind® Phenyl	1 year
Sartobind® Cassettes (all four membrane types)	1 year
1.5 Sartocube®	
Sartocube® Cassettes	3 years
Sartocon® Cassettes	3 years
Sartocon® Slice Cassettes	3 years
Sartocon® Slice 200 Cassettes	3 years
Sartocon® Slice Disposable Cassettes	2 years
Sartocon® Slice 50 Cassettes	2 years
Sartocon® self-contained devices and assemblies	1 year
Sartocube® self-contained devices and assemblies	1 year
1.6 Virosart®	
Virosart® HC, CPV and Max	3 years
Virosart® HF	2 years
Virosart® Media	1 year
Minisart® HC / CPV	1 year
1.7 Transfer Sets	
FFU Sterile Filter Transfer Set, gamma irradiated	2 years
FSL Sterile Sensor Transfer Set, gamma irradiated	2 years
FTS Sterile Transfer Set, autoclaved	3 years
1.8 Filter Assembly MMR / VMR	
MaxiCaps® MR Filter Assembly	2 years
MaxiCaps® MR Virosart HF Sterile Filter Assembly	2 years
MaxiCaps® MR Virosart Media Sterile Filter Assembly	1 year
1.9 Cultibag® STR Filter Lines	
DS001K-SBFLI (STR 500-1000)	3 years
DS001K-SBFLO (STR 500-1000)	3 years
DS200L-SBFLI (STR 50-200)	3 years
DS200L-SBFLO (STR 50-200)	3 years
DS002K-SBFLI (STR 2000)	3 years
DS002K-SBFLO (STR 2000)	3 years

2. Expiry date on labels and certificates

For each process filter, a clear indication of the shelf life is given on the Quality Assurance Certificate and on the label and, if applied to the product, in the Data Matrix code as a "use before date". Consequently, process filters must be used before the month indicated on the certificate.

Example: If the "use before date" states "06 / 2023" the filters must be used until the end of May 2023.

3. Storage conditions of Sartorius process filters

For proper storage of Sartorius process filters, the following conditions are required to guarantee the functionality of these products over the specified time period, which corresponds to the recommended shelf lives:

- Storage in a closed, dry area
- Temperature: 5°C – 40°C, frost-free (valid for all Sartorius process filters, except for Sartobind® and Sartocon® self-contained)
- Temperature for Sartobind®: 15°C – 25°C
- Temperature for Sartocon® self-contained: 2°C – 35°C
- Humidity: 10% – 75%
- No direct solar radiation
- No direct contact with moisture
- Prevention of any mechanical influence or damage

Products with damaged packaging should be discarded.

4. Extending the shelf lives of sterile delivered standard process filter

As described under chapter 1.1 to 1.3, sterile delivered standard process filters such as Capsules, MidiCaps® and MaxiCaps®/ T-Style MaxiCaps® have a shelf life of 3 years compared to a total shelf life of non-sterile delivered standard process filters of 5 years (except Sartolon).

The shelf life of sterile delivered (autoclaved) Capsules, MidiCaps® and MaxiCaps®/ T-Style MaxiCaps® is related to the sterility of the standard process filter and to the integrity of the sterile packaging. If these standard process filters expire after 3 years of storage (following the storage conditions in chapter 3) it is possible to extend the shelf life by an additional 2 years to reach a maximum total shelf life of 5 years by resterilization (autoclaving).

Please consider that Sartopore® 2 and Sartobran® P filters have to be wetted prior to autoclaving, whereas Sartopore® Platinum as well as Sartofluor® filters do not have to be wetted prior the autoclaving procedure.

5. Reusability of Sartocon® Cassettes

Sartocon® Cassettes are re-usable with appropriate cleaning and handling as described in the Validation Guide and user manual. The number of using cycles for re-usable products fully depends on the respective process parameters. Therefore, a guaranteed lifetime cannot be given.

Designated single-use products are designed and qualified to be used once only. For Sartocon® Slice, Slice 200, Sartocon® and Sartocube® the latest date of first use is 3 years. For Slice 50 and Slice Disposable the latest date of first use is 2 years.

Sartocon® Slice / Sartocube® self-contained devices are gamma irradiated and must be used before the “use before date” to ensure sterility.

Remarks:

Sartorius process filters have to be handled in accordance with the recommendations given in the Validation Guides and instructions for use which accompany each process filter. As long as the recommendations given in these official documents are adhered to, these devices will maintain their performance in line with the information provided in the Validation Guides and within the shelf life periods stated above.

Furthermore, the sterility and stated shelf life of sterile delivered products are only valid as long as these products are kept in their original packaging. The stated shelf lives do not represent a general guarantee according to German Civil Code § 443 BGB.

If you have any further question, please do not hesitate to contact us. We thank you for your trust and your continuous use of Sartorius process filters and look forward to assisting you.

Sincerely
Sartorius Stedim Biotech GmbH
Service Quality Assurance



i.A. Tabea Streil

Product Management Filtration



i. A. Andre Grebe