

Section 1: Supplier and Product Description	
This appendix is associated with Module 1: Company Information for: Company Name: Sartorius AG. Please refer to module 1.	
This appendix is associated with Module 2: Site Information for: Sartorius Stedim Biotech GmbH, Goettingen, Germany (SSB) and/or Sartorius Stedim Filters Inc., Yauco, Puerto Rico (SSF) Please refer to module 2.	
<p>For SSB, Goettingen, Germany: The head of quality associated with this site is: Dr. Anna Vreemann Contact Information (e-mail/phone): Anna.vreemann@sartorius.com +49 551 308 0</p> <p>For SSF, Yauco, Puerto Rico: The head of quality associated with this site is: Maribel Marcano Contact Information (e-mail/phone): maribel.marcano@sartorius.com +1 787 856 5020</p>	
1.1	<p>Product Name: Sartobind STIC® PA : [92STPA42... 96STPA42... 98STPA42...] Sartobind® Q : [92IEXQ42... 96IEXQ42... 98IEQ42...] Sartobind® S : [92IEXS42... 96IEXS42... 98IEXS42...] Sartobind® Phenyl : [92HICP42... 96HICP... 98HICP...] Sartobind® Rapid A: [96R-PA19.... 98R-PA19...] Sartobran® P [523...] Sartoclean®CA: [562...] Sartoclean® GF: [560...] Sartoclean® Jumbo Star: [563...] Sartoclear®: [29CDL... 29CS... 29MDL... 29MS... 29XDL... 29XS... 29Z...] Sartocon®: [Cassettes (PESU): [302146... 302154...] [Cassettes (Hydrosart®): [302186... 302144...] [Slice 200]® Slice Slice ECO(PESU): [308146... 305154... 308154... 305146... 308146AL 305146AL... 3M5146...3M8146] [Slice 200] ® Slice Slice ECO(Hydrosart®): [308144... 305186... 305144... 308186... 3M8144... 3M5144...] [ECO (PESU): [3M2146...] [ECO (Hydrosart®): [3M2144...] [Slices Disposables (PESU): [306146...] [Slices Cassettes (Hydrosart®): [305144...] [Slice 50 ECO (Hydrosart®): [3D9144...] [Slice 50 ECO(PESU):[3D9146...] [Self- Contained (PESU):[SFA...SUM-146...] SFA-SU-146...] SFA-SU- 154...] [Self-Contained (Hydrosart®): [SFA-SUM-144...] SFA-SU-144...] SFM-OP-144... 3D5144...] [Slice Self Contained (PESU)]:</p>

	<p>Sartocube® Cassettes (Hydrosart®): [302144... 302186...] Sartocube® Polyetersulfone: [302146... 302154] Sartocube® ECO (PESU): [3M2146...] ECO (Hydrosart®); [3M2144...] Sartocube® SC (PESU): [SFM-AQ-146... SFB-LY-146...] [Sartocube® SC(Hydrosart®): [SFM-AQ-144... SFM-OP-144...]</p> <p>Sartofluor® HR: [517...] Sartofluor® LG [518...], Sartofluor®GA: [518...] Sartoguard® PES [547...] Sartoguard® GF [548...] Sartoguard®NF [546...], Sartopore® Platinum [549...] Sartopore®2 [544...] Sartopore® 2 XLI: [544...] Sartopore®2 XLG : [544...] Sartopore® XLM : [544...] Sartopore® 2 HF : [544...] Sartopore®Air [519...] Midisart® (Midisart® 2000) : [178...] Midisart® BV :[178...] Sartopore® air Midisart®: [178...] Sartopure® IND: [550...] Sartopure® PP3: [505...] Sartopure® PP2: [559...] Sartopure® GF [555...] Midisart® [178...] Minisart® [165.../175.../S65.../S75...], Sartosteel [570...], Aerosart [515...], Aquasart Plus: [538...] Aquasart Plus XL: [54B...] Aquasart PS [541...], Sartobev® [531...], Sartocool®PS [530...], Vinosart® PS [542...], Sartavent P [552...], Fibersart [313...], OPTA® SFT Sterile connector [640.../641...], Sterile Sensor Transfer Set [FSL...], Sartopore® 2 Sterile Transfer Set [FTS...], Sterile Filter Transfer Set [FFU...] Biosart 100 Media [16400-02...], Unisart® [UN1.../1UN1.../1UN9.../2UNY...], CultiBag STR [DS...] product family</p> <p>The above-mentioned filtration products can be produced at Sartorius Stedim Biotech GmbH, Germany and/or at Sartorius Stedim Filters Inc., Puerto Rico. Manufacture under the same product specifications. See attached Worldwide Quality Commitment and attached Statement on Equivalence.</p> <p>Note: The product families marked in orange are only manufactured in Germany.</p>
1.2	Product Description: Filtration products
1.3	Supplier's Product/Article Number: Please refer to 1.1.
1.4	CAS # (if applicable): N/A
1.5	Compendial Grade(s) – if applicable: N/A

1.6	<p>Please check the category the product is applicable to.</p> <p><input type="checkbox"/> API; Chemical/Reagent; Excipient</p> <p><input type="checkbox"/> Equipment (e.g. Fermenter; Laboratory Equipment)</p> <p><input type="checkbox"/> Control and SCADA Systems, Computerized Systems</p> <p><input type="checkbox"/> Packaging Component (container, bottles, caps, bags)</p> <p><input checked="" type="checkbox"/> Single Use Equipment (Storing and Fermentation Bags, Filters, Liquid Handling sets)</p> <p><input checked="" type="checkbox"/> Auxiliars; Multi use Equipment (multi use filters, tubing, clips)</p> <p><input type="checkbox"/> Other:</p>
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Please check here if additional documents are attached.

Section 2: Material Source		
<p>Please attach a flowchart or a short description indicating the manufacturing process for this material. <input type="checkbox"/></p> <p>See Attachment <input checked="" type="checkbox"/> Proprietary (not applicable)</p>		
2.1	<p>Are only synthetic origin materials used during the manufacturing process?</p> <p>NOTE: Consider all starting materials, reagents, chromatographic media, buffers, enzymes, fermentation broth, etc.</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>The cellulose is solved from wood and acetylated, then cast as membrane and maybe regenerated. This is hardly a plant material anymore but an organic source.</p>
2.1a	<p>If Yes, then provide country of manufacture for starting material, if applicable.</p> <p>This can be reviewed during an audit in Germany and/or Puerto Rico. Most of our filter membranes are manufactured on site.</p>	
2.1b	<p>If No, specify the origin of the starting materials used during the manufacturing process. Check all that are applicable.</p> <p><input type="checkbox"/> Plant</p> <p><input type="checkbox"/> Animal</p> <p><input type="checkbox"/> Human</p> <p><input type="checkbox"/> Natural (Inorganic or Organic, non-synthesis or mined)</p> <p><input type="checkbox"/> Fermentation (culture media doesn't contain any animal or human derived components)</p> <p><input type="checkbox"/> Fermentation (culture media contains the following animal or human derived components)</p>	
2.2	<p>Please check all that apply:</p>	
2.2a	<p>Human, animal and/or plant origin materials are used as raw materials in the manufacturing process?</p> <p><input type="checkbox"/> Yes (if yes indicate material type below)</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Human</p> <p><input type="checkbox"/> Animal</p> <p><input type="checkbox"/> Plant</p>	



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2.2b	Human, animal and/or plant origin materials are used in the manufacturing process (i.e. lubricants, reagents, cleaning agents, processing aids, enzymes, culture media, slip agents, or other) <input checked="" type="checkbox"/> Yes (if yes indicate material type below) <input type="checkbox"/> No <input type="checkbox"/> Human <input checked="" type="checkbox"/> Animal <input type="checkbox"/> Plant Please refer to the BSE/TSE Statement.	
2.3	Is the product of biological origin and NOT affected by Genetically Modified Organisms?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A Please refer to the GMO Statement.
2.3a	If Yes, do you monitor the non-GMO origin?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
2.3b	If Yes, do you perform analytical controls to verify the non-GMO status?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
2.3c	If Yes, do you have a non-GMO traceability or identity preservation (IP) program?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
Comments		
(Please reference appropriate question number for any additional comments)		
N/A		

Section 3:	
Supply Chain Management Procedures and Risk	
Definitions:	
<p>A distributor facilitates movement of the product through the supply chain from manufacturing to the end user. A distributor is not conducting process steps that are required to bring the product to a near finish form. A distributor may be packaging, testing, passing material through, acting as a Toller etc.</p> <p>A manufacturer conducts the process steps required to bring the product to a near finish form with no further changes to form, fit or function. The product may go on to be filled, packaged, labeled, etc., by the manufacturer.</p>	
3.1	<p>Are you considered a distributor or the manufacturer of the listed product?</p> <p><input type="checkbox"/> Distributor (only) Complete all of Section 3 only. Provide a copy of this Module 3 to the Manufacturer to be filled out in its entirety and returned to Customer requesting information).</p> <p><input type="checkbox"/> Manufacturer (only) Fill out entire Module.</p> <p><input checked="" type="checkbox"/> Both Fill out entire Module</p>



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3.1a	<p>If you are a distributor, what action are you taking with the product? Check all that apply. Check N/A if you are the direct manufacturer or both manufacturer and distributor.</p> <p><input type="checkbox"/> Pass Through (no testing)</p> <p><input type="checkbox"/> Re-labelled with testing</p> <p><input type="checkbox"/> Re-packaged with testing</p> <p><input type="checkbox"/> Re-packaged/Re-label (no testing)</p> <p><input type="checkbox"/> Does not touch the product or store the product in any way, acts as a facilitator to get product to end user</p> <p><input type="checkbox"/> Other:</p> <p><input checked="" type="checkbox"/> N/A</p>
3.1b	<p>If you are not the manufacturer and the name and address of the manufacturing site is different than that provided on page 1 of this questionnaire, please provide the name and address of the manufacturing site below:</p> <p>Name: N/A</p> <p>Address: N/A</p> <p>State/Region: N/A</p> <p>Country: N/A</p> <p>Postal Code: N/A</p> <p><input checked="" type="checkbox"/> Please check here if there are multiple manufacturer or manufacturing sites please attach a separate document with those additional details. Please refer to SC Memo for Sartorius manufacturing network oversight and to RX-360 SAQs of the site in your scope.</p>
3.1c	<p>If the above information is proprietary, could it be disclosed if a Source Disclosure Agreement or some other sort of legal confidentiality agreement were to be put in place?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A</p>
3.1d	<p>Are there any additional distributors in the supply chain?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>
3.2	<p>The following questions concern risk based upon Supplier Qualification Program.</p> <p>Do you have a Supplier Qualification program for qualification for the following?</p> <p><input checked="" type="checkbox"/> Raw materials</p> <p><input checked="" type="checkbox"/> Service suppliers</p> <p><input checked="" type="checkbox"/> 3rd party manufacturers Please refer to the Sartorius Vendor Management Program Statement.</p>
<p>If you've selected one or more of the above, please complete the following:</p>	
3.2a	<p>Is the supply chain of material traceable from manufacturing through distribution to the customer?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>
3.2b	<p>Is complete testing performed against the supplier's Certificate of Analysis?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>

3.2c	Which of the following tools are used as a part of supplier qualification? Check all that apply.	
	<input checked="" type="checkbox"/> Questionnaire/self-assessment <input checked="" type="checkbox"/> On-site audit including 3 rd party/Rx-360 audit program <input checked="" type="checkbox"/> Long Term Relationship <input checked="" type="checkbox"/> If other, please provide justification: Risk-based approach .	
3.2d	Do you include certificate of Country of Origin in your qualification program?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Additional product specific modules may be sent to address additional or follow up questions.		
****NOTE: If you are distributor only stop here. ****		
Comments (Please reference appropriate question number for any additional comments)		
N/A		
Section 4: General Manufacturing Questions		
4.1	Are ICH guidelines followed concerning the specific use of residual solvents, metal catalysts or reagents during the manufacturing and release?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
4.1.a	Are metal catalysts or reagents used during production?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
4.1.b	Are residual solvents (ICH Q3C) present in the product(s)? If yes, please comment on the solvents: See http://www.ich.org/home.html	<input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A For most of our products, the answer applies "No". For some products residual solvents may remain. Please refer to the Residual Solvents Statements.
4.1.c	Are metal residues /elemental impurities (ICH Q3D) present in the product? See http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q3D/Q3D_Step_4.pdf	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not Tested Please refer to the Elemental Impurities Statement and the Extractables Guide.
4.2	Are there any allergens in the product, in raw materials used in the product or in contact with the product?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
4.3	Is natural rubber latex used in the manufacturing or the formulation of the product?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
4.4	Are there aflatoxines (mold contamination) or mycotoxins caused by the product itself or in raw materials used in the manufacturing?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

4.5	Do any of the products contain any substance from the list of Substances of Very High Concern (SVHC) published by the European Chemicals Agency (ECHA) in a concentration above 0.1% by weight? See- https://echa.europa.eu/home	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.6	If applicable to your product, do you comply with 2011/65/EU (RoHS)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
4.7	In addition to the categories marked above, does the product comes in contact with any of the following materials during manufacturing? Check all that apply: <input checked="" type="checkbox"/> Synthetic origin <input type="checkbox"/> Biologic/Animal Origin <input type="checkbox"/> Plant Origin <input type="checkbox"/> Other:	
4.8	Are flame retardants used in the manufacturing or handling process?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
4.9	Are any of the following used in the manufacturing or handling process? Please check all that apply. <input type="checkbox"/> Polyhalogenated dibenzodioxins <input type="checkbox"/> Dibenzofurans <input type="checkbox"/> Biphenyls <input type="checkbox"/> Phtalates <input checked="" type="checkbox"/> Bisphenol A (BPA) <input type="checkbox"/> Asbestos <input checked="" type="checkbox"/> Ionizing radiation For SSB Goettingen and SSF: Sterilization of applicable products (gamma irradiation) <input checked="" type="checkbox"/> N/A For SSF Yauco and SSB Goettingen: Sterilization of applicable products (hot steam)	
4.10	Are antibiotics manufactured and/or stored in the same facility? <input type="checkbox"/> Manufactured <input type="checkbox"/> Stored <input checked="" type="checkbox"/> N/A	
4.10a	If Yes, what types the risk mitigation actions are conducted to prevent cross contamination? N/A	
4.11	Is the product manufactured in dedicated equipment? Note: Based upon how this question is answered additional information may be in module Manufacturing and Cleaning.	<input checked="" type="checkbox"/> Yes for SSB Goettingen <input checked="" type="checkbox"/> No for SSF Yauco
4.12	Is the product manufactured in an animal component free dedicated facility?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.13	Are there any parts of the manufacturing process that use contract manufacturing?	<input checked="" type="checkbox"/> Yes for SSB Goettingen <input type="checkbox"/> No
4.13a	If yes, what type of contract manufacturing is performed? <input checked="" type="checkbox"/> Components for SSB Goettingen <input type="checkbox"/> Finished product with company logo <input type="checkbox"/> Finished product without company logo	



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<input checked="" type="checkbox"/> Other: Sterilization (gamma and EtO for SSB)		
If applicable, please provide any current certifications available concerning the above questions. Additional product specific modules may be sent to address additional or follow up questions.		
<p align="center">Comments (Please reference appropriate question number for any additional comments)</p>		
N/A		
<p align="center">Section 5: Change Notification</p>		
5.1	Is there a change control notification process available that includes changes of the manufacturing process, manufacturing site or source of starting material?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.1a	Supplier hereby agrees to notify the customer of any changes in sources of supply or information provided in this questionnaire.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A Other: Information about relevant changes according to a change matrix of an internal procedure depending on the type of change. Please refer to the attached Change Notification Statement.
5.1b	Does enrollment of change notification (check all that apply): <input checked="" type="checkbox"/> Occur automatically based upon purchase? <input type="checkbox"/> Require establishing change notification or Quality Agreement? <input checked="" type="checkbox"/> Require providing contact information as to where the change notification should be sent? New contact information or contact updates should be sent to changenotification_AB@sartorius.com Other: N/A	
5.1c	Is timeframe for customer notification before change implementation specified in internal procedures?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5.1d	Does your change notification process require customer approval?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<p align="center">Comments (Please reference appropriate question number for any additional comments)</p>		
Information about relevant changes according to a change matrix of an internal procedure depending on the type of change. Please refer to the attached Change Notification Statement.		

Section 6: Material Specific Health/Safety		
6.1	Is a Material Safety Data Sheet available for this material? If yes please attach with completed questionnaire.	<input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No Please refer to the MSDS Statement for Sartocou Cassettes_Sartocubes and the Material Safety Data Sheet Statement.
6.2	Are there special handling or storage requirements for this material? If yes please specify. Manuals are provided along with the product.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Please refer to the Shelf Life Statement which includes the storage conditions.
6.3	Does this material have a REACH registration reference number? If yes, please provide: N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Based on the REACH directive the mentioned articles are defined as articles. A registration is not necessary.
6.4	Does this material have a REACH pre-registration reference number? If yes, please provide: N/A	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
6.5	Does the company have a recognized Health/Safety/Environmental Management system e.g. OHSAS 18001 and/or ISO14001? If yes, please attach a copy of certificates. If no, please answer 6.5.a and b.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
6.5a	Does your manufacturing site comply with all local and national environmental and safety legislation applicable to your company?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
6.5b	Please provide details of current environmental and/or safety programs in place e.g. waste minimization, energy efficiency, national license, etc. For SSB Goettingen ISO 14001 and ISO 50001 For SSF Yauco ISO 14001	
6.6	Have there been any fines, penalties, prosecutions in the last 3 years of any kind on this product? Given the size and scope of our organization a diligent inquiry has been made and to the best of our knowledge we are not aware of same.	
6.7	How do you meet the dangerous goods/packaging requirements for your materials? N/A. No dangerous goods, see refer to point 6.1.	
Comments (Please reference appropriate question number for any additional comments)		
6.5: The ISO certificates can be downloaded from our homepage https://www.sartorius.com/en/legal-documents		



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SARTORIUS

I (Supplier) confirm that the information provided in this questionnaire is correct and can be verified.

Printed Name: [Aida Santos/ Daniel Wist](#)

Signature: _____ *j. A. Wist*

Date: [2023-10-24](#)

Title: [Quality Customer Support- ST / Quality Professional- ST](#)

Telephone Number: [Goettingen: +49 551 308 0 / Yauco: +1 787 856 5020](#)

Email address: Customer.Questionnaires@Sartorius.com

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