

Standard Terms and Conditions of Sale for Confidence® Validation Services

1. General

- 1.1 These general terms and conditions of Sale for Validation Services ("GTCs") apply to the sale of Validation Services (as hereinafter defined) as set out in the quotation provided by the Sartorius entity ("Sartorius"), to which these terms are appended the ("Quotation"). The customer named in such Quotation shall be referred to as the "Customer". Sartorius shall supply and the Customer has elected to purchase Validation Services in accordance with and based on these GTCs, which along with the Quotation, shall be referred to as the "Agreement". In the event of conflict between the terms in these GTCs and the Quotation, the terms in the Quotation shall prevail. Validation Services may be performed by Sartorius or a Sartorius Affiliate. "Sartorius Affiliate" refers to any individual or entity directly or indirectly (i) controlling, (ii) controlled by, or (iii) under common control with the ultimate parent company of such Party. For purposes of this definition, "control" means the direct or indirect ownership of more than fifty percent (50%) of the outstanding voting rights, or the right to control the policy decisions of the respective entity. Sartorius may engage contractors or agents to perform aspects of the Validation Services.
- 1.2 The Agreement comprises the entire agreement between the parties, and supersedes all prior or contemporaneous understandings, agreements, negotiations, representations and warranties, and communications, both written and oral, with respect to Confidence Validation Services. This Agreement supersedes and prevails over any of Customer's terms and conditions, regardless of when or how Customer has submitted such other terms. Fulfilment of Customer's order does not constitute acceptance of Customer's terms and conditions and does not serve to modify or amend this Agreement. No variation to these GTCs shall be binding unless agreed in writing between the authorized Representatives of the Customer and Sartorius. Any additional or different terms not so expressly accepted by both parties in writing are hereby expressly rejected and are void.
- 1.3 Assigned project numbers provided in the Quotation will be used for project tracking. Project numbers must appear on all purchase orders, documentation, and correspondence related to the Validation Services.

2. Services

- 2.1 These GTCs apply to the non-regulated contracted services to be provided by Sartorius as more particularly described in the Quote ("Confidence® Validation Services"). Sartorius does not represent, warrant, or undertake that the Validation Services will be available for order unless and until it issues a Quotation, receives a customer purchase order for such Quotation ("PO"), and accepts such Customer PO with the issuance of an Order Acknowledgement.
- 2.2 Sartorius's employees or agents are not authorized to make any representations concerning the Validation Services unless confirmed by Sartorius in writing. In entering into the Agreement, Customer acknowledges that it does not rely on, and waives any claim for breach of any such representations which are not so confirmed.
- 2.3 Any advice or recommendation given by Sartorius or its employees or agents to the Customer or its employees or agents as to the storage, application or use of the Validation Services which is not confirmed in writing by Sartorius is followed or acted upon entirely at the Customer's own risk, and accordingly Sartorius shall not be liable for any such advice or recommendation which is not so confirmed. Marketing and other promotional material relating to the Validation Services are illustrative only and do not form part of the Agreement. Customer agrees that, in submitting an order, it has not relied on any representation or statements by Sartorius other than those expressly set out in the Agreement.
- 2.4 Any typographical, clerical or other error or omission in any sales literature, Quotation, price list, acceptance of offer, invoice or other document or information issued by Sartorius, including Sartorius's website, shall be subject to correction without any liability on the part of Sartorius.
- 2.5 No order which has been accepted by Sartorius may be cancelled by the Customer except in accordance with the terms set forth in these GTCs and with the agreement in writing by Sartorius and on the condition that Customer shall indemnify, defend and hold harmless Sartorius in full against all loss (including loss of profit), costs (including

the cost of all labor and materials used), damages, charges and expenses incurred by Sartorius as a result of cancellation.

- 2.6 Any Sartorius Quotation that does not include an acceptance deadline may be revoked by Sartorius at any time unless Sartorius receives written confirmation of acceptance by the Customer within ninety (90) days from the Quotation date.
- 2.7 For the avoidance of doubt, Customer is solely and exclusively responsible for the selection of the Validation Services to be performed as well as any other related (non) regulatory determination. Customer shall have the ultimate responsibility for determining which Validation Services are required in its process to meet requirements applicable to Customer's process, including but not limited to, any relevant regulatory requirements including the requirements of any Marketing Authorization. Customer hereby agrees and acknowledges that any overview provided by Sartorius of the various services is not included in and does not form part of the Validation Services.
- 2.8 In the event a Customer requests a change to scope of the Validation Services, Customer shall communicate such change request in writing to Sartorius. Customer shall be responsible for meeting the costs of any additional work required as a result of any such change (as further outlined in these GTCs), and the estimated timelines for completion of the relevant Validation Services shall be adjusted by Sartorius to take account of any such change.
- 2.9 Any change in the details or the assumptions upon which the process protocol or testing parameters for the Validation Services is based (including but not limited to changes in an agreed starting date for the Validation Services or suspension of the Validation Services by the Customer) may require changes in the price and /or timelines and shall require a written amendment (a "Change Order"). The Change Order shall detail the requested changes to the applicable task, responsibility, duty, price, timelines or other relevant matters. The Change Order will become effective upon the execution of the Change Order by both parties, and Sartorius will be given a reasonable period of time within which to implement the changes. Both parties agree to act in good faith and promptly when considering a Change Order request by the other party. Sartorius reserves the right to postpone effecting material changes in the scope of the Validation Services until such time as the parties agree to and execute the corresponding Change Order. There is a limit of two (2) Change Orders for each Validation Study. Should further Change Orders be required, Customer may be invoiced an additional fee for each additional Change Order.

3. Test Materials

- 3.1 It shall be the responsibility of the Customer to provide Sartorius with the relevant data and sufficient test materials and/or Customer reagents to enable Sartorius to perform the Validation Services, together with all information relevant to the same, including but not limited to safety information and other or further information requested by Sartorius which Sartorius may request to enable Sartorius to make the necessary arrangements for the receipt, safe storage, handling and use of the test materials and Customer reagents. Customer shall ship materials to Sartorius in accordance with DAP INCOTERMS 2020 Sartorius Destination.
- 3.2 In the event the test material or Customer reagents require a regulatory license or other formal consent for their transport to Sartorius' premises, storage, handling or use, it is an essential condition of the Agreement that the Customer shall provide to Sartorius all information reasonably required to enable Sartorius to obtain any such regulatory license or other consent where Sartorius has a statutory or regulatory obligation to do so, and otherwise the Customer shall provide Sartorius with evidence that all such regulatory licenses and other formal consents for such transport, storage, handling and use of the test materials and Customer reagents, as applicable, are in place. Sartorius shall use reasonable efforts to obtain any such regulatory licenses and other formal consents where it has a regulatory or statutory duty to do so and commencement of Validation Services shall be subject to all such necessary regulatory licenses and consents being in place. If it is not possible to obtain any required regulatory licenses or consents after reasonable efforts have been made to do so, either party shall be entitled to terminate these GTCs subject to payment to Sartorius of all sums due up to and until the time of such cancellation.
- 3.3 It shall be the responsibility of the Customer to ensure that all data, test materials and Customer reagents shall be fit for purpose and in the event that the Validation Services requires to be repeated as a result of any defect, error

or omission in the data and/or defect in the test materials or Customer reagents, the Customer shall be responsible for all additional costs arising therefrom.

- 3.4 The Customer warrants that it has, and shall continue to have throughout the duration of the Agreement, the necessary authority, including third party consents, to provide the data, test material and Customer reagents with relevant information thereon to Sartorius and to enable use by Sartorius of the data, test materials and Customer reagents in provision of the Validation Services without breach of any third party intellectual property rights, and Sartorius shall have no obligation to establish that such authority and consents exist.
- 3.5 The Customer shall ensure that it has sufficient test materials and Customer reagents to permit the repeat of the Validation Services where required and the Customer shall provide Sartorius with sufficient replacement test materials and Customer reagents, as applicable, to enable the affected study to be repeated. In the event of the test materials or Customer reagents being lost or damaged so as to be unfit for use through the fault of Sartorius or in the event of the Validation Services or any part thereof requiring to be repeated through the fault of Sartorius and requiring additional test materials or Customer reagents to be able to do so, Sartorius bear the cost of transporting the replacement test materials and Customer reagents to the Sartorius' premises.
- 3.6 On completion of the Validation Services (as determined by Sartorius) the relevant test materials, and where applicable, Customer reagents, not utilized in performance of the Validation Services, shall be retained by Sartorius for a period of one month following such completion and thereafter they shall be destroyed unless the Customer specifies, as part of the Validation Services protocol, that it requires the return or the storage of such test materials or Customer reagents, and where applicable, any such Customer reagents and/or test materials will be returned to the Customer at its cost and pursuant to FCA INCOTERMS 2020 Customer Destination.
- 3.7 Validation of test filters or components manufactured by companies other than Sartorius must be supplied by the Customer.
- 3.8 Safety Data Sheets (SDS) or waivers must be submitted with each Process Operating Parameters ("POP") form by the Customer.

4. Validation Services; Specific Terms

- 4.1 Amendments to protocols are limited to two revisions. Should further revisions be required, an additional fee, as specified in the Quotation, will be applied for each additional requested revision.
- 4.2 A shipping authorization form, indicating product volume requirements, instructions for safe handling and labeling will be issued to the Customer.
- 4.3 For testing to be scheduled, the Test Protocol signature page must be returned to Sartorius, along with the test fluid sample.
- 4.4 Test results will be issued as a draft validation report in electronic format. Except as otherwise stated in the Quotation, the study will be invoiced for the amount quoted upon issuance of the draft report. Sartorius can make up to two amendments to the draft report (unless otherwise specified) as requested by the Customer. Should further revisions to the draft or final report be required, Customer will be invoiced for an additional fee as specified in the Quotation.

5. Pricing

- 5.1 All Prices are exclusive of Value Added Tax (or equivalent sales tax) sales, withholding or other tax (other than income tax to which Sartorius may be subject), which shall be payable in addition by the Customer. If any amount due under the Agreement is subject to such Value Added Tax, sales, withholding or any other tax which has the effect of reducing the amount of money which Sartorius would have been entitled to receive or retain from the Customer under the Agreement but for such tax, the Customer will, at Sartorius's request, pay to Sartorius such additional sum at the rate for the time being prescribed by law for that tax. Customers within the EU shall be obligated to indicate their Value Added Tax identification number.
- 5.2 Unless otherwise stated in the Quotation, freight and insurance are not included in the price.

- 5.3 Charges for services not covered by the Agreement will be invoiced separately at the time of occurrence or delivery and at Sartorius' then prevailing rates.
- 5.4 Sartorius reserves the right to submit separate invoices for each project initiated. Without prejudice to the foregoing, in the event that any part of the Price remains outstanding beyond the due date, Sartorius shall be entitled, on providing 14 days written notice to the Customer of intention to suspend provision of the Validation Services and in the event of the outstanding sums remaining unsettled after the said 14 day period, to suspend provision of the Validation Services until settlement of the outstanding sum, and any delay in completing the Validation Services as a result thereof shall be the responsibility of the Customer.

6. Delivery

- 6.1 Any delivery dates or study completion dates indicated herein or otherwise set by Sartorius are estimates only. They do not operate to bind Sartorius to the dates indicated unless specifically agreed in writing by Sartorius. If Customer defaults in its obligations, Sartorius may suspend any additional partial or whole Validation Services unless and until Customer cures such default.

7. Payment

- 7.1 Customer shall pay to Sartorius the invoice price of the Validation Services sold hereunder, in full and without any deduction or set-off of any kind whatsoever, within 30 days after the invoice date in the currency specified by Sartorius, unless otherwise stated in the Quotation.
- 7.2 If the amounts owing are in the U.S. dollars, interest will be charged daily on past due amounts at a varying rate of the lesser of (i) two percentage points per annum above the prime (sometimes called base) rate of interest announced by Citibank, N.A., from time to time and (ii) the maximum rate of interest allowed by law. If the amounts owing are in a currency other than U.S. dollars, interest on past due accounts will be charged at the rate of interest customarily charged by Sartorius on credit sales to its customers in the currency specified.
- 7.3 If Sartorius shall conclude in its sole discretion that the financial condition of Customer at any time jeopardizes its ability to perform its obligations hereunder, Sartorius may require cash payments or additional security satisfactory to Sartorius before further performance by Sartorius. Customer's failure to timely pay any invoice shall operate to make all other invoices of Sartorius immediately due and payable and, at the discretion of Sartorius, shall be grounds for cancellation of any further performance by Sartorius. The receipt by Sartorius of part payment shall not constitute a waiver of any of Sartorius's rights set forth herein or provided by law, including the right to terminate this Agreement.

8. Inventions and Discoveries

- 8.1 Except as expressly outlined in this Section 8, all inventions, discoveries, know-how and other information in any form, including the Results, that are first created, developed, written, conceived, or made by Sartorius as a result of performance of the Validation Services and which relate to the Test Materials ("**Customer IP**") shall be the property of the Customer. Customer IP shall not include all purification and associated testing methodology, processes or procedures and technology, skills and knowhow relating thereto (hereinafter defined as "**New Sartorius IP**") which New Sartorius IP shall belong exclusively to Sartorius. Sartorius shall provide such assistance as shall be reasonably required by the Customer to protect the Customer IP including assisting Customer in its application for patents and other protection, subject always to the Customer being solely and fully responsible for any and all costs associated with same.
- 8.2 In addition to the aforesaid, Sartorius shall retain all rights to its pre-existing purification and associated testing methodology, processes and procedures, technology, skills, information and know-how that Sartorius uses in providing the Validation Services ("**Pre-existing Sartorius IP**") and no rights to use any Pre-existing Sartorius IP or New Sartorius IP for testing purposes or to transfer the Pre-existing Sartorius IP or New Sartorius IP to any third party are granted to the Customer under these Terms and Conditions. However, the Customer shall be entitled to disclose to any relevant regulatory authority the Pre-existing Sartorius IP and New Sartorius IP to the extent necessary to meet the requirements to obtain any Marketing Authorization as well as to obtain permission from such regulatory authority for the development, production and release of Customer's product. Any such rights to

use or disclose such Pre-existing Sartorius IP or New Sartorius IP, (including disclosure to regulatory authorities as aforementioned) shall require the prior written approval of Sartorius.

9. Warranty, Liability

- 9.1 All warranties in relation to the Validation Services, whether express or implied, except as set forth in these Terms and Conditions, are hereby excluded to the fullest extent permitted by law. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH THESE TERMS AND CONDITIONS, SARTORIUS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE VALIDATION SERVICES, INCLUDING, BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
- 9.2 Sartorius gives no warranty that the supply of Validation Services does not infringe any intellectual property rights of third parties.
- 9.3 Except as outlined in Section 9.7, Sartorius shall not be liable for any special, indirect, incidental, consequential or exemplary loss or damage including loss of profit or anticipated profit, business, contracts or goodwill, whether notice of the likelihood of such damage is given to Sartorius and whether arising, without limitation, through breach of contract, negligence, strict liability in delict, tort, warranty or statutory duty, howsoever arising, which the Customer or any third party may sustain in connection with the Validation Services supplied or to be supplied under these Terms and Conditions.
- 9.4 Notwithstanding anything else herein to the contrary, the aggregate liability of Sartorius, including but not limited to claims alleging or relating to breach of contract, negligence, strict liability, tort, warranty or statutory duty, howsoever arising, and for any losses, damages, costs or expenses suffered or incurred by the Customer arising from or in connection with the Validation Services shall be limited to fifty (50%) percent of price paid by the Customer in connection with the Validation Services that are subject to the claim.
- 9.5 Without prejudice to the terms in Section 9.4, in the event that Sartorius should make an error in the performance of the Validation Services and such mistake arises through the fault of Sartorius, Sartorius shall, at its sole option, have the opportunity, in full settlement of all sums due by it to the Customer in respect of such error, to either:
- a) repeat that part of the Validation Services which is defective as a result of such error (where reasonably practicable to do so); or
 - b) refund to the Customer (if such sum has already been paid by the Customer) or otherwise deduct from the price, that part of the price which relates to the defective Validation Services.
The obligations of Sartorius contained in this Section 9.5 shall be conditional upon the error not having arisen as a result of:
 - (i) any failure of the Customer to provide all information relevant to the data, test materials and Customer reagents in accordance with the terms in Section 3.1; or
 - (ii) the data, test materials and Customer reagents being unfit for purpose or defective pursuant to Condition 3.3.
- 9.6 Customer shall fully indemnify, defend and hold harmless Sartorius and its affiliates, and their respective directors, officers, employees, sub-contractors and agents ("Indemnified Persons") from and against any and all losses, claims, costs, damages, actions, demands, expenses and liabilities whatsoever (including without limitation special, indirect, incidental, consequential or exemplary loss or damage including loss of profit or anticipated profit, business, contracts or goodwill) (collectively hereinafter known as "**Claims**") which any Indemnified Person or any other third party may suffer or incur in any jurisdiction whatsoever including, without limitation, any Claims (i) arising from any infringement of any intellectual property rights of any third party arising from any data, test materials, Customer reagents, product, study plan, specification or instruction furnished by Customer; (ii) arising from the death or personal injury of an Indemnified Persons or any third party caused by the data, test materials, Customer reagents, product, specification or other information or instruction furnished by the Customer; (iii) relating to or arising from Customer's breach of its obligations hereunder; and which relate to or arise from Sartorius's performance of the Validation Services, except to the extent that any such Claims arise solely as a result of the material breach or negligence of Sartorius.

- 9.7 Sartorius shall give the Customer prompt written notice of any such Claim or lawsuit (including a copy thereof) served upon it and shall fully cooperate with the Customer and its legal representatives, at Customer's expense, in the investigation of any matter which is the subject of indemnification. Customer shall not settle or resolve any such Claim or lawsuit without Sartorius' prior written consent and Sartorius shall not unreasonably withhold its approval of the settlement of any claim, liability or action covered by the indemnification provisions.

10. Insurance

- 10.1 Each party shall maintain comprehensive general liability insurance, including product liability insurance, property damage insurance, public liability insurance, completed operations insurance and contractual liability insurance, designating each party as an additional named insured, and have such coverage and limits and be issued by such company as each party shall deem reasonably adequate for its protection. Each party shall, within ten (10) calendar days after each parties request therefore, furnish certificates of insurance, issued by the applicable insurers, confirming the coverages, limits and expiration dates of the respective insurance policies.

11. Confidentiality

- 11.1 Neither party (hereinafter defined as the "Recipient") shall disclose to any third party or use for any purpose other than as expressly described herein, any information received by it from the other party relating to the Validation Services or otherwise relating to a project ("Confidential Information") without the express written consent of the party disclosing such Confidential Information (the "Discloser"), the Discloser being the sole proprietor of its Confidential Information. Notwithstanding the aforesaid, for the sake of clarity, information relating to the Customer's product, Test Materials or Results (but excluding Pre-existing Sartorius IP or New Sartorius IP, which is and shall remain the sole Confidential Information of Sartorius) shall be the sole property of the Customer. The parties shall respectively ensure that access to the Confidential Information disclosed to it is restricted to only those persons who have a need to know in respect of a bona fide use of the Confidential Information in connection with the Services and that such persons are bound by equivalent confidentiality obligations.
- 11.2 The obligations of confidentiality set out in Section 11.1 above shall not apply to Confidential Information to the extent that it can be shown to be:
- a) already in the public domain at the point of first disclosure to the Recipient or it subsequently gets into the public domain other than through the Recipient's disclosure;
 - b) was already known to the Recipient at point of first disclosure to the Recipient and is not covered under a pre-existing confidentiality obligation between the Discloser and the Recipient restricting disclosure;
 - c) received by the Recipient from a third party not under an obligation of confidentiality to the Discloser;
 - d) required to be disclosed by the Recipient to a court of competent jurisdiction, or competent tribunal or by the lawful requirement of any regulatory agency, but subject always to the Recipient providing notice of such requirement to the Discloser as soon as reasonably practicable, if legally entitled to do so, and providing reasonable assistance to the Discloser, at the Discloser's cost, to restrict disclosure;
 - e) where the Customer is the Recipient, required for submission to any competent regulatory agency or other government body as part of the Recipient's regulatory submission or licence application relating to the Product; or
 - f) where Sartorius is the Recipient, reasonably required to be disclosed to an affiliate of Sartorius; or to an approved subcontractor; for the purposes of use in providing subcontracted services forming part of the Validation Services subject to the said subcontractor being bound by equivalent confidentiality obligations with respect to such disclosed Confidential Information.

12. Termination

- 12.1 Outside the reasonable control of Sartorius, due to the nature of the Validation Services which involves the use of biological materials, there may arise technical difficulties ("Circumstances") that prevent the completion of the Validation Services. In the event such Circumstances arise, Sartorius and the Customer shall use reasonable efforts

to mutually find a solution to enable provision of the Validation Services. In the event a solution cannot be found within a period of twenty-eight (28) days of the occurrence of the Circumstances, either party shall then be entitled to terminate the affected part of the Validation Services by serving written notice on the other party. Notwithstanding any such notice of termination or termination of the Agreement, Customer shall promptly and fully remit the cost for all work performed by Sartorius up to the date of termination, together with all costs incurred by Sartorius as a result of such termination (excluding costs of laboratory space reserved for the terminated Validation Services). Sartorius will act reasonably to minimize any such costs chargeable to the Customer.

- 12.2 Either party shall be entitled to immediately terminate the performance of Validation Services by written notice to the other if:
- a) the other party commits any material breach of any of the provisions of these Terms and Conditions and, in the case of a breach which is capable of remedy, fails to remedy same within 30 days after receipt of a written notice giving full particulars of the breach and requiring it to be remedied; or
 - b) the other party becomes insolvent or apparently insolvent or makes any voluntary arrangement with its creditors generally, or becomes subject to an administration order; or
 - c) the other party goes into liquidation (except for the purposes of amalgamation or reconstruction and in such a manner that the company resulting therefrom is solvent and effectively agrees to be bound by or assume the obligations imposed on the other party under these Terms and Conditions); or
 - d) the other party ceases, or threatens to cease, to carry on business; or
 - e) if the Customer is acquired by a competitor of Sartorius.
- 12.3 For the purposes of Section 12.2 (i) a breach shall be considered capable of remedy if the party in breach can comply with the provision in question in all respects other than as to the time of performance (provided that time of performance is not of the essence).
- 12.4 Sartorius shall be entitled to terminate this Agreement on written notice in the event the Customer fails to provide Sartorius with the signed and approved test protocol, process/test fluid sample and other related information and materials required for testing within 9 months from Sartorius's receipt of the PO from Customer, unless otherwise specified in the quotation.
- 12.5 Termination of this Agreement, for whatever reason, shall not affect the accrued rights of the parties under this Agreement as at the date of termination and, in particular but without limitation, the right to recover damages from the other as provided for in this Agreement; nor shall termination affect the continuance in force of any provision contained within this Agreement which is expressly or by implication intended to continue in force after such termination.
- 12.6 If Customer seeks to cancel or terminate this Agreement after commencement of the testing phase, Sartorius shall be entitled to be compensated for any work or service performed for Customer up to and until the effective date of termination, which amounts may include all direct costs of labor, raw materials and parts purchased or contracted to be purchased and overhead costs incurred by Sartorius. Customer agrees that Sartorius' calculation of such costs shall be accepted by the parties hereto.
- 12.7 If the Customer seeks to cancel or terminate the Validation Services after Sartorius has initiated drafting and/or issuance of the test protocol, Sartorius will invoice Customer a percentage of the total cost, in accordance with the cancellation pricing terms set forth in the Quotation.

13. Force Majeure

- 13.1 If either party is prevented or delayed from or in performing any of its obligations under these Terms and Conditions by Force Majeure, as hereinafter defined, then it may notify the other party of the circumstances constituting the Force Majeure and of the obligations of performance which are thereby delayed or prevented, and the party giving notice shall thereupon be excused the performance or performance, as the case may be, of such obligations for so long as the circumstances of prevention or delay may continue, subject to the party giving notice and using all reasonable efforts to bring to an end such circumstances as soon as reasonably practicable.

For the purposes of this condition 'Force Majeure' means any circumstances beyond the reasonable control of the affected party including (without prejudice to the generality of the foregoing) war, industrial dispute, strike, lockout, riot, malicious damage, fire, storm, flood, act of God, accident, pandemic, epidemic, lock-down, shelter-in-place or non-availability or shortage of material or labor, failure by any sub-contractor or supplier to perform, failure of equipment, any statute, rule, bylaw, order, regulation, or requisition made or issued by any government department, local or other duly constituted authority. Should such period of prevention or delay continue for a period in excess of 60 days either party may terminate the affected part of the Validation Services.

14. Miscellaneous

- 14.1 The invalidity or unenforceability of any one or more of the terms of this form shall not affect the validity and enforceability of the remaining terms hereof.
- 14.2 The failure of either party to insist upon strict performance by the other party of any term of this form or to exercise any right hereunder shall not be deemed to be a modification of any term hereof or a waiver of the future performance of any such term.
- 14.3 The Agreement shall be governed by the laws of the Country of the Sartorius entity offering the Sale for Validation Services. In the event the Sartorius entity is located in the US this would need to be "State of New York" excluding its provisions governing conflicts of laws. The United Nations Convention on Contracts for the International Sale of Goods (CISG) of April 11, 1980 shall not apply.
- 14.4 In the event Sartorius is located in the United States and its territories, or Canada, the Parties agree that any disputes under this Agreement shall be brought and maintained in the state courts located in the State of New York, Suffolk County and in the Federal courts of the United States located in the Eastern District of New York and the parties hereby consent to the personal jurisdiction and exclusive venue of these courts.
- 14.5 In the event Customer and Sartorius are located in the European Union, any disputes under this Agreement must be brought before the local courts of the registered office of Sartorius, and the Parties hereby consent to the personal jurisdiction and exclusive venue of these courts.
- 14.6 If section 14.4 and 14.5 are not applicable, the following shall apply: In the event one of the Parties is located outside the European Union, all dispute, controversy or claim arising out of or relating to this Agreement or its validity shall be finally settled according to the ICC Rules of Arbitration without recourse to the ordinary courts of law (except as regards interlocutory relief). The place of arbitration is the place of the registered office of Sartorius. The arbitral proceedings are to be held in English language.
- 14.7 Customer shall comply with all applicable local, state, national and international laws and regulations, including but not limited to the applicable customs and export control regulations such as US re-export, embargo regulations and sanction programs.

Customer shall inform Sartorius in writing of all foreign trade master data including, at a minimum the information specified below, as may be applicable. Such information shall be provided at the time of purchase order acceptance (e.g. in the order confirmation) but no later than at the point of the shipment of the test materials (e.g. by printing the information on the delivery note). In case of any changes to the foreign master trade data, Customer will inform SARTORIUS in writing immediately.

- i. The country of origin (non-preferential origin) according to the rules of origin from the World Customs Organization (WCO)
- ii. A statistical goods number (Harmonized System Code) based on the tariff nomenclature from the World Customs Organization (WCO)
- iii. The Export Control Classification Number (ECCN) according to the EC Dual-Use regulation (No. 428/2009 including latest updates) or comparable international lists like German Ausfuhrliste, UK Strategic Export Control List, Swiss Güterkontrollverordnung, Indian SCOMET regulation, Singapore Strategic Goods Control List, as well as a ECCN related to the US Export Administration Regulations (EAR) or any other applicable law or regulation

- 14.8 Customer and Sartorius each hereby irrevocably waive all rights to trial by jury in any action, proceeding or counterclaim arising out of or relating to this agreement.
- 14.9 Orders are not assignable or transferable, in whole or in part, without the express written consent of Sartorius.
- 14.10 Any marketing, promotion or other publicity material, whether written or in electronic form, that refers to Sartorius, its affiliates, its products, or to these GTCs must be approved by Sartorius prior to its use or release.
- 14.11 Sartorius, or its affiliates, is the owner of certain proprietary brand names, trademarks, trade names, logos and other intellectual property. Except as otherwise expressly permitted by Sartorius, no use of Sartorius's or its affiliates' brand names, trademarks, trade names, logos or other intellectual property is permitted, nor the adoption, use or registration of any words, phrases or symbols so closely resembling any of Sartorius' or its affiliates' brand names, trademarks, trade names, logos or other intellectual property as to be apt to lead to confusion or uncertainty, or to impair or infringe the same in any manner, or to imply any endorsement by Sartorius of another entity's products or services allowed.
- 14.12 Nothing in this Agreement shall be deemed to constitute a partnership between the parties or to make either party the agent of the other party for any purpose. Furthermore, each party shall remain solely responsible for its own acts, statements, engagements, performances, products (in the case of Sartorius subject to the other terms of these GTCs in relation to the Validation Services), and personnel.
- 14.13 Nothing in this document is intended to create any rights in third parties against Sartorius.
- 14.14 Any notice required or permitted to be given by either party to the other under these GTC shall be in writing addressed to that other party at its registered office or principal place of business or such other address as may at the relevant time have been notified pursuant to this provision to the party giving the notice.
- 14.15 No waiver by Sartorius of any breach of the Agreement by the Customer shall be considered as a waiver of any subsequent breach of the same or any other provision.