

Sartorius Stedim Biotech GmbH, 37070 Göttingen

Changenotification_ab@sartorius.com

February 8th, 2024

Scope Extension

ECR 33619: ST Certificates - Removal of cGMP Claim

Dear Valued Customer,

You have been notified about the change ECR: 33619 in the letter dated March 10th, 2023 regarding ST Certificates - Removal of cGMP Claim.

This letter is to inform you that some references will be added to the scope. This list of additional references can be found in Appendix 1.

In addition, the claim is not applicable to Sartorius and has been removed from all Separation Technology products, even if they are not mentioned in Appendix

We thank you for your trust and continued use of Sartorius products, and we look forward to assisting you in managing this change.

Sincerely,

DocuSigned by: DocuSigned by: Kristin Menzel Jonas Lyeune

Signierzeit: 2024-02-16 | 12:03:03 MEZ 672B288C286D4203AD59767A32BD2B58

Name des Unterzeichners: Kristin Menzell Nom du signataire : Jonas Lejeune Signiergrund: Ich habe dieses Dokument verfasstif de la signature : J'approuve ce document Heure de signature : 2024-02-16 | 09:49:28 CET

4E190FC098A54650A1D7C762C6CF7663

Kristin Menzel Technical Quality Assurance CT Sartorius Stedim Biotech GmbH

Jonas Lejeune Manager of Project Quality Sartorius Stedim FMT S.A.S. Sartorius Stedim Biotech GmbH August-Spindler-Straße 11 37079 Göttingen, Germany Telefon +49 551 308 0 Fax +49 551 308 3289 www.sartorius.com

Sitz der Gesellschaft: Göttingen Registergericht: Amtsgericht Göttingen HRB-Nr. 200266

Geschäftsführer: Michaela Pischke, Dr. Helge Henning

Vorsitzender des Aufsichtsrates: Dr. Joachim Kreuzburg