

Date: August 28th, 2018

Dear valued Customer,

This letter is a follow-up to an information previously sent in July 2017 regarding the relocation of manufacturing capabilities from our production site in Eppelheim, Germany to our Center of Excellence for BioMonitoring in Molsheim, France.

We kindly remind you that as of 01 November 2017, in an effort to improve notification processes and to provide you with only those notifications that are meaningful to your specific organization, Customer Change Notifications are solely sent based on Quality Agreements or Change Notification Commitments (CNC) that customers have set up with us.

Further details regarding the relocation of manufacturing capabilities from Eppelheim, Germany to Molsheim, France will be sent upon transfer advancement through official Change Notification Process only. If you wish to be notified about further change details, please make sure you have set up a Quality Agreement or Change Notification Commitment for the products listed in the appendix.

To obtain a Customer Notification Commitment, please contact your local account manager or use the "contact us" information located on our website.

Information regarding Manufacturing Transfer of Ready-to-Use Media Products from Merck Life Science GmbH, Eppelheim, Germany (see list in Appendix)

Our company announced plans to reorganize its Life Science operations in Germany, Switzerland and France to drive operational excellence and improve efficiency by simplifying the network.

The business will develop centers of excellence in key European locations. This transformation will allow us to deliver more high-quality products faster and more efficiently than before.

The Molsheim manufacturing site it is recognized as a Center of Excellence for capacity considerations, existing infrastructure, cross-functional know-how available on site and quality. The site is already an important production location with capabilities for global product supply and distribution of a broad range of products, including Ready to Use culture media in bottles and plates.

The products manufactured at Merck Life Science GmbH will be transferred from our production site in Eppelheim, Germany to our Center of Excellence for BioMonitoring in Molsheim, France. Equivalence of the manufacturing processes will be validated and documented for each product group.

Simultaneously to the relocation at the Molsheim, France manufacturing site, warehousing and distribution activities from Eppelheim, Germany logistic hub will be taken over by our distribution center in Strasbourg, France.



Table 2 gives detailed additional information related to this change in

- manufacturing site
- distribution center location
- harmonized temperature range for cold storage conditions

To ensure supply continuity during the respective transfer period, the residual shelf life for the affected products could be adapted to a lower range.

Implementation schedule

Current project planning suggests the transfer of Ready-to-Use culture media products to Molsheim will begin in 2019, with a completion by 2020 for the full portfolio. The transfer timeline is different depending on product group. You find the planned timelines in the table below.

Overall, as detailed below, we identified the following product categories:

- **standard products**
The supply of products manufactured in Eppelheim will be maintained during the transition period. Transferred products are planned to be manufactured in the new location in accordance with implementation dates indicated in Table 1. Until full consumption of remaining inventories, you might receive products manufactured either in Eppelheim or in Molsheim.
For the **mycoplasma media**, a separate notification will be sent to the affected customers to provide additional information.
- **customized products** (contract manufacturing)
Customized products with valid manufacturing contracts will be transferred. There will be a separate communication. To verify your respective contract status and get more details about the transfer, please contact your local representative.

The manufacturing lines will be qualified using an established change control procedure. Full validation and qualification reports will be available at implementation date for consultation when auditing our Molsheim France facilities. Validation summaries for the manufacturing lines at the Molsheim location are planned to be available upon request for each product group according to implementation timelines indicated in table 1.

Attachments

Table 1: Standard products transfer schedule

Table 2: Additional Information related to Change in Manufacturing Site

We provide this information to the best of our knowledge and ability, without liability for mistakes or omissions.

If you would like more information about this change, or to request a Change Notification Commitment for any affected product, please contact your local representative or use the link www.merckmillipore.com/offices for our website to obtain the phone number and/or email address of your local office.



Table 1: Standard products transfer schedule

Transferred products are planned to be manufactured in the new location in accordance with transfer schedules indicated in the table below.

Material code	Material description	Planned Implementation date
1460000020	VRBD Agar - LI 30ml 0185e-20p	01 December 2019
1460000120	VRBD Agar - LI 30ml 0185e-120p	01 December 2019
1460020020	TSA w. LTHTh - LI 30ml 030820e-20p	01 December 2019
1460020120	TSA w. LTHTh - LI 30ml 030820e-120p	01 December 2019
1460030020	SDA w. Cm acc. EP - LI 03350e-20p	01 December 2019
1460030120	SDA w. Cm acc. EP - LI 03350e-120p	01 December 2019
1460050020	SDA w. LTHTh - ICR 30ml 03544e-20p	01 December 2019
1460050120	SDA w. LTHTh - ICR 30ml 03544e-120p	01 December 2019
1460060020	FREY Agar acc. EP 20PC	01 August 2020
1460070020	FRIIS Agar acc. EP 090e-20p	01 August 2020
1460150020	TSA w. LTHC - LI 30ml 030821e-20p	01 December 2019
1460150120	TSA w. LTHC - LI 30ml 030821e-120p	01 December 2019
1460160120	Sab.Dex.A sel. +LTHTh - ICR 03545e-120p	01 December 2019
1460220020	MacConkey A-LI acc. EP 30ml 0126e-20p	01 December 2019
1460220120	MacConkey A-LI acc. EP 30ml 0126e-120p	01 December 2019
1460230020	Mannitol Salt Agar - LI 30ml 0128e-20p	01 December 2019
1460230120	Mannitol Salt Agar - LI 30ml 0128e-120p	01 December 2019
1460240020	Pseudomonas Agar P - LI 30ml 01102e-20p	01 December 2019
1460280020	SDA - LI acc. EP 03300e-20p	01 December 2019
1460280120	SDA - LI acc. EP 03300e-120p	01 December 2019
1460290020	HAYFLICK Agar acc. EP 20PC	01 August 2020
1460480020	Cetrimide A -LI acc. EP 30ml 0110e-20p	01 December 2019
1460480120	Cetrimide A -LI acc. EP 30ml 0110e-120p	01 December 2019
1460490020	R2A Agar chromogenic - LI 0177e-20p	01 December 2019
1460520020	Sab-Gluc-A w. LTHTh -LI 30ml 03540e-20p	01 December 2019
1460520120	Sab-Gluc-A w. LTHTh -LI 30ml 03540e-120p	01 December 2019
1460660020	MacConkey Agar Pharm. 126ph-20p	01 December 2019



Material code	Material description	Planned Implementation date
1460690020	TSA w. LTHTh - ICR 30ml 030826e-20p	01 May 2019
1460690120	TSA w. LTHTh - ICR 30ml 030826e-120p	01 May 2019
1460730020	XLD Agar - LI EP+USP 30ml 0152e-20p	01 December 2019
1460730120	XLD Agar - LI EP+USP 30ml 0152e-120p	01 December 2019
1460740020	R3A Agar - LI 30ml 0173e-20p	01 December 2019
1460750020	R2A Agar - LI EP 30ml 0178e-20p	01 December 2019
1460750120	R2A Agar - LI EP 30ml 0178e-120p	01 December 2019
1460760020	TSA + LT + Cephase - ICR 03085e-20p	01 December 2019
1460760120	TSA + LT + Cephase - ICR 03085e-120p	01 December 2019
1460810120	Sab-Dextr-A. w. LT -ICR 30ml 03542e-120p	01 December 2019
1460930120	Chocolate Agar +LTH - SDV 055-120p	01 December 2019
1461210020	ReadyTube™ 18 Yeast Extract 168r-20p	01 December 2019
1461210100	ReadyTube™ 18 Yeast Extract 168r-100p	01 December 2019
1461370020	ReadyPlate™ Baird Parker Agar ISO 6888	01 December 2019
1461370120	ReadyPlate™ Baird Parker Agar ISO 6888	01 December 2019
1461390100	Thioglycollate Medium acc EP 2170r-100p	01 December 2019
1461410020	NaCl-Pept-B. 9.9ml blue EP 1935r-20p	01 December 2019
1461420020	ReadyTube™ 9 BPW ISO 6579,ISO 6887	01 December 2019
1461450020	GSP-A. (Pseudomon./Aeromon.) 191e-20p	01 December 2019
1461510020	Malt Extract Agar 194e-20p	01 August 2020
1461540020	Contact Agar Plate Count-RT 238e-20p	01 August 2020
1461600020	ReadyPlate™ MYP ISO 7932, 21871	01 December 2019
1461610020	ReadyPlate™ DG18 agar ISO 21527	01 December 2019
1461610120	ReadyPlate™ DG18 agar ISO 21527	01 December 2019
1461750100	NaCl-Pept-B. with LTH 9ml 380r-100p	01 December 2019
1461800001	FRIIS Liquid Medium acc. EP 390100-1p	01 August 2020
1461810020	Rappaport Vassil.-B. acc. EP 3922r-20p	01 December 2019
1461810100	Rappaport Vassil.-B. acc. EP 3922r-100p	01 December 2019
1461850020	Lactose TTC A. w. Tergitol-7 166e-20p	01 December 2019
1461860020	ReadyPlate™ CHROM Listeria Agar ISO 11290	01 December 2019
1461890020	ReadyPlate™ CT BPA ISO 6888 241e-20p	01 August 2020



Material code	Material description	Planned Implementation date
1461910020	Contact A. Malt Extract - RT 250e-20p	01 August 2020
1461930100	NaCl (phys.) 9ml 2084r-100p	01 December 2019
1461950020	Tr. Soy Cont. A. w. LT-ICR 2284e-20p	01 August 2020
1461950200	Tr. Soy Cont. A. w. LT-ICR 2284e-200p	01 August 2020
1461960100	NaCl Peptone Buffer 9.0ml EP 1936r-100p	01 December 2019
1462010020	SDA Contact w. LTHTh - ICR 25130e-20p	01 August 2020
1462010200	SDA Contact w. LTHTh - ICR 25130e-200p	01 August 2020
1462080020	ReadyTube™ 10 Fraser Broth ISO 11290	01 December 2019
1462080100	ReadyTube™ 10 Fraser Broth ISO 11290	01 December 2019
1462170100	NaCl (phys.) 10ml 2080r-100p	01 December 2019
1462190100	Mossel Broth acc. EP+USP 2193r-100p	01 December 2019
1462200100	Thioglycollate Med. acc. EP 2171r-100p	01 December 2019
1462310020	Tr. Soy Cont. A w. LTHTh-ICR 2283e-20p	01 August 2020
1462310200	Tr. Soy Cont. A w. LTHTh-ICR 2283e-200p	01 August 2020
1462360020	ReadyPlate™ SDA ISO, FDA-BAM, EP+USP	01 December 2019
1462360120	ReadyPlate™ SDA ISO, FDA-BAM, EP+USP	01 December 2019
1462370020	Sab-Gluc.(4%)-Agar w. LHT 3541e-20p	01 December 2019
1462400020	Cont. A. Tr. Soy-RT EP+USP 235e-20p	01 August 2020
1462530020	ReadyPlate™ CT VRBG Agar ISO 21528	01 August 2020
1462560100	Standard I Nutrient Agar 303e-100p	01 December 2019
1462660020	ReadyPlate™ CT DG 18 Agar ISO 21527	01 August 2020
1462690020	Plate Count Agar 306e-20p	01 December 2019
1462830020	Tryptic Soy Broth w. LTHTh 373r-20p	01 December 2019
1462830100	Tryptic Soy Broth w. LTHTh 373r-100p	01 December 2019
1462850020	Tryptic Soy Agar +LTH 30821e-20p	01 December 2019
1462890100	DEV Nutrient Agar 3872r-100p	01 December 2019
1463030100	SDA acc. EP+USP 3351r-100p	01 December 2019
1463110001	FREY Liquid Medium acc. EP 397100-1p	01 August 2020
1463130006	R2A Agar acc. EP 477200-6p	01 August 2020
1463160001	Tryp. Soy Broth acc. EP+USP 502 10l b-1p	01 December 2019
1463170010	Tryptic Soy Broth acc EP+USP 502100d-10p	01 August 2020



Material code	Material description	Planned Implementation date
1463210020	Bile Esculin Azide Agar 167e-20p	01 December 2019
1463250006	ReadyTube™1000 Giolitti Cantoni ISO	01 August 2020
1463260020	ReadyPlate™ CHROM TBX Agar ISO 16649	01 December 2019
1463270100	NaCl Peptone Broth 9ml 1934r-100p	01 December 2019
1463320001	Vegetable Peptone Broth 404 10l b-1p	01 December 2019
1463330010	Thioglycoll. B. 100ml clear 490100sd-10p	01 August 2020
1463340006	Tryptic Soy Broth acc EP+USP 502090-W-6p	01 August 2020
1463350006	Tryptic Soy Broth acc EP+USP 502100 B-6p	01 August 2020
1463420006	Tryptic Soy Broth 750ml 502750sd-6p	01 August 2020
1463480020	Yeast Glucose Cm Agar (YGC) 3590e-20p	01 December 2019
1463520010	ReadyTube™ 100 Yeast Extract ISO 6222	01 August 2020
1463530006	Mod. Tween Lethen B. (MLBT) 486090-W-6p	01 August 2020
1463570006	Tryptic Soy B. acc. EP+USP 502100-W-6p	01 August 2020
1463600006	Buff. NaCl-Pept. Sol. acc EP 514090-B-6p	01 August 2020
1463640006	Ready Tube™ 200 MRS Medium ISO 15214	01 August 2020
1463650006	Plate Count Agar 200ml 508200-6p	01 August 2020
1463660010	Sabouraud Dextrose B. (SDB) 509100-10p	01 August 2020
1463670010	Buff. NaCl-Pept. Sol. acc EP 514100-10p	01 August 2020
1463680006	Buff. NaCl-Pept. Sol. acc EP 5141000-6p	01 August 2020
1463710006	Buff NaCl-Pept.Sol.+0.1%Tw80 518090-W-6p	01 August 2020
1463720006	MacConkey Broth acc. EP 526100-B-6p	01 August 2020
1463740006	ReadyTube™ 400 Yeast Extract ISO 6222	01 August 2020
1463750006	Tryptic Soy Agar EP+USP 501400-6p	01 August 2020
1463790006	Tryptic Soy B. acc. EP+USP 5021000-6p	01 August 2020
1463800010	Tryptic Soy B. acc. EP+USP 502100sd-10p	01 August 2020
1463810006	NaCl-Pept-B. + 0.1% Tween 80 5181000-6p	01 August 2020
1463820006	MacConkey Broth acc. EP 5261000-6p	01 August 2020
1463830006	MacConkey B. acc EP wide m. 526100-W-6p	01 August 2020
1463850010	Fl. Thioglyc. Med acc EP+USP 510100-10p	01 August 2020
1463860010	Fl. Thioglyc. Med acc EP+USP 510100sd-10	01 August 2020
1463870006	Fluid Thioglycollate Medium 510750sd-6p	01 August 2020



Material code	Material description	Planned Implementation date
1463920006	Sabouraud Dextrose A. acc EP 548400-6p	01 August 2020
1463930006	Sab. Dextrose (4%) A. acc EP 548200-6p	01 August 2020
1463940006	Sab. Dextr.(4%) Agar w. Cm 550200-6p	01 August 2020
1463970010	Fluid D acc. USP 577100d-10p	01 August 2020
1463980006	Fluid A acc. USP 5791000sd-6p	01 August 2020
1464030006	ReadyTube™1000 BPW ISO 6579, ISO 6887	01 August 2020
1464040006	ReadyTube™225 BPW ISO 6579, ISO 6887	01 August 2020
1464050006	Milk Plate Count Agar 200ml 508201-6p	01 August 2020
1464060010	Fl. Thioglyc. Med acc EP+USP 510100d-10p	01 August 2020
1464070006	Buff. NaCl-Pept. Sol. acc EP 514090-W-6p	01 August 2020
1464080006	Buff. NaCl-Pept. Sol. acc EP 514300d-6p	01 August 2020
1464130006	Malachite Green Broth 562050-W-6p	01 August 2020
1464150006	Fluid A acc. USP 579300d-6p	01 August 2020
1464190006	Buff. NaCl-Pept. Sol. acc EP 514200-6p	01 August 2020
1464230006	ReadyTube™ 200 VRBL Agar ISO 4832	01 August 2020
1464250006	Orange Serum Agar 540200-6p	01 August 2020
1464270020	MacConkey Cont. A.-RT acc EP 240e-20p	01 August 2020
1464290020	Tryptic Soy A. (Tubes 18ml) 3071r-20p	01 December 2019
1464290100	Tryptic Soy A. (Tubes 18ml) 3071r-100p	01 December 2019
1464310020	ReadyPlate™ TSA ISO, FDA-BAM, EP+USP	01 December 2019
1464310100	ReadyPlate™ TSA ISO, FDA-BAM, EP+USP	01 December 2019
1464320100	Tryptic Soy Broth acc EP+USP 3080r-100p	01 December 2019
1464340006	Mossel Broth (EE Broth) 5281000-6p	01 August 2020
1464350006	ReadyTube™ 200 VRBG Agar ISO 21528	01 August 2020
1464520001	HAYFLICK Liquid Med. acc. EP 393100-1p	01 August 2020
1464560010	Thioglycollate B. 0.1l clear 490100d-10p	01 August 2020
1464570006	Tryptic Soy Agar EP+USP 501200-6p	01 August 2020
1464580010	Tryptic Soy Broth acc EP+USP 502100-10p	01 August 2020
1464610010	MacConkey B. acc. EP/USP/JP 526100-10p	01 August 2020
1464630010	Mossel Broth acc. EP+USP 528101-10p	01 August 2020
1464650006	Yeast Glucose Cm Agar 545200-6p	01 August 2020



Material code	Material description	Planned Implementation date
1464690006	Fluid D acc. USP 577500sd-6p	01 August 2020
1464700010	Fluid A acc. USP Septum 579100d-10p	01 August 2020
1464710006	NaCl Peptone Buffer w. LTHTh 591090-W-6p	01 August 2020
1464760006	ReadyTube™225 Half Fraser ISO 11290	01 August 2020
1464800010	Buff. NaCl-Pept. Sol. acc EP 514090-10p	01 August 2020
1464810006	NaCl-Peptone Solution w. TLH 5901000-6p	01 August 2020
1464820006	NaCl Peptone Buffer w. LTH 590450-6p	01 August 2020
1464830006	Fluid D acc. USP 577300d-6p	01 August 2020
1464840006	Tryptic Soy Broth +LT 90ml 582090 B-6p	01 August 2020
1464880006	Fluid A acc. USP 579500sd-6p	01 August 2020
1464920010	TSB + TLHC (Inactivator B.) 58200090-10p	01 August 2020
1464950010	Cas.Pept.Lec.Polysorb.B. USP 585090-10p	01 August 2020
1464960010	Mod Tween Lethen Broth 90ml 586090-10p	01 August 2020
1465010020	Sab-Gluc-Cont. A +LTHTh-ICR+ 850-20p	01 August 2020
1465010200	Sab-Gluc-Cont. A +LTHTh-ICR+ 850-200p	01 August 2020
1465020001	Rack for contact plates 63140-1p	01 June 2020
1465090125	Transp. Bags (25x5) -sterile 60050-125p	01 June 2020
1465190001	Rack for sedimentation pl. 63141-1p	01 June 2020
1465220006	NaCl-Pept-Buff. +LTH wide n. 590090-W-6p	01 August 2020
1465250001	Bottle Rack 6 x 1000ml 70219-1p	01 June 2020
1465260001	Bottle Rack 15 x 100ml 70220-1p	01 June 2020
1465290100	ICR-Swab 60515-100p	01 December 2019
1465300001	Swab Rack 63142-1p	01 December 2019
1465380020	SDA Contact +LTHTh sel-ICR+ 851-20p	01 August 2020
1465380200	SDA Contact +LTHTh sel-ICR+ 851-200p	01 August 2020
1465390200	TS-Cont. +LT +Cephase-ICR+ 823-200p	01 August 2020
1465490020	SDA Contact +Cm - RT+ 862-20p	01 August 2020
1465540020	TSA Contact +LTH - RT+ 860-20p	01 August 2020
1465550020	Chocolate Cont. A. +LTH-ICR+ 835-20p	01 August 2020
1465590020	Columbia Blood Agar Pharm. 109ph-20p	01 December 2019
1465590100	Columbia Blood Agar Pharm. 109ph-100p	01 December 2019



Material code	Material description	Planned Implementation date
1465770020	Sab. Dextr. Agar - ICR 30ml 03541e-20p	01 December 2019
1465770120	Sab. Dextr. Agar - ICR 30ml 03541e-120p	01 December 2019
1465860006	MTLB w. 0.07% Lec. 487090W-6p	01 August 2020
1466220100	ReadyTube™12 MSRVS Medium ISO 6579	01 December 2019
1466280006	Isopropylmyristate - irradi. 444360-6p	01 June 2020
1466830020	TSA LTHTh 90mm ICR+ 0720-20P	01 December 2019
1466830120	TSA LTHTh 90mm ICR+ 0720-120P	01 December 2019
1466840020	TSA LT 90mm ICR+ 0721-20P	01 December 2019
1466840120	TSA LT 90mm ICR+ 0721-120P	01 December 2019
1466850020	TSA 90mm ICR+ 0700-20P	01 December 2019
1466850120	TSA 90mm ICR+ 0700-120P	01 December 2019
1466890020	ReadyPlate™ CHROM CCA ISO 9308	01 December 2019
1466900120	Min. Glucose Agar Ames Test - 120P	01 December 2019
1466940020	ReadyTube™10 RVS Broth ISO 6579	01 December 2019
1466970020	Neutralizer A - Contact-ICR+ 20P	01 August 2020
1466970200	Neutralizer A - Contact-ICR+ 200P	01 August 2020
1467000120	TSA +LT +Cephase-ICR+ 90mm -120P	01 December 2019
1467020020	SDA +LTHTh-ICR+ 90mm -20P	01 December 2019
1467020120	SDA +LTHTh-ICR+ 90mm -120P	01 December 2019
1467030020	SDA +LT-ICR+ 90mm -20P	01 December 2019
1467030120	SDA +LT-ICR+ 90mm -120P	01 December 2019
1467040020	SDA sel.+LTHTh-ICR+ 90mm -20P	01 December 2019
1467040120	SDA sel.+LTHTh-ICR+ 90mm -120P	01 December 2019
1467110100	ReadyPlate™ PEMBA ISO 21871 -100P	01 December 2019
1467160120	MTLA - LI 120P	01 December 2019
1467170020	ReadyPlate™ MRS Medium ISO 15214	01 December 2019
1467180020	ReadyPlate™ TCBS agar ISO 21872, FDA-BAM	01 December 2019
1467190020	Rambach Agar 20p	01 December 2019
1467190100	Rambach Agar 100p	01 December 2019
1467290020	Malt Extract Agar with Cm 20p	01 December 2019
1467510020	ReadyPlate™ XLD Agar ISO 6579 20PC	01 December 2019



Material code	Material description	Planned Implementation date
1467530100	IsoBag TSA+LTHThio Contact+ 1 PC	01 March 2019
1467540100	IsoBag TSA+LTHTh Contact 1 PC	01 August 2020
1467550080	IsoBag TSA+LTHTh Settle+ 1 PC	01 December 2019
1467560080	IsoBag TSA+LTHTh Settle 1 PC	01 May 2019
1467570020	ReadyPlate™ 55 CCA ISO 9308 20P	01 August 2020
1467570200	ReadyPlate™ 55 CCA ISO 9308 200PC	01 August 2020
1467580150	ReadyPlate™ 55 KIT CCA ISO 9308	01 August 2020
1467610020	ReadyPlate™ 55 TGE Agar 20P	01 August 2020
1467620150	ReadyPlate™55 KIT TGE Agar 150P	01 August 2020
1467630020	ReadyPlate™ 55 Plate Count Agar	01 August 2020
1467640150	ReadyPlate™ 55 KIT Plate Count Agar	01 August 2020
1467650020	ReadyPlate™ 55 Slanetz&Bartley ISO 7899	01 August 2020
1467660150	ReadyPlate™ 55 KIT Slanetz & Bartley ISO	01 August 2020
1467670020	ReadyPlate™ 55 CN Agar ISO 16266	01 August 2020
1467680150	ReadyPlate™ 55 KIT CN Agar ISO 16266	01 August 2020
1467690020	ReadyPlate™ 55 m-Green Agar 20P	01 August 2020
1467700150	ReadyPlate™ 55 KIT m-Green Agar	01 August 2020
1467780018	TSA with LTHTh - ICR 15cm 18PC	01 August 2020
1467830020	TSA w. LTHThio cont.-ICR+ -20P	01 March 2019
1467830200	TSA w. LTHThio cont.-ICR+ -200P	01 March 2019
1467840100	IsoBag TSA+LT Contact 1 PC	01 August 2020
1467850080	IsoBag TSA+LT Settle+ 1 PC	01 December 2019
1467860020	TSA w. LTHThio sedi.-ICR -20P	01 May 2019
1467860120	TSA w. LTHThio sedi.-ICR -120P	01 May 2019
1467870020	TSA w. LTHThio sedi.-ICR+ 20P	01 December 2019
1467870120	TSA w. LTHThio sedi.-ICR+ 120P	01 December 2019
1467970020	TSA w. LTHThio cont.-ICR -20P	01 August 2020
1467970200	TSA w. LTHThio cont.-ICR -200P	01 August 2020
1467980020	TSA w. Pen. LTHThio cont. ICR+	01 August 2020
1467980200	TSA w. Pen. LTHThio cont. ICR+	01 August 2020
1467990020	TSA w. Pen. LTHThio sedi. ICR	01 December 2019



Material code	Material description	Planned Implementation date
1467990120	TSA w. Pen. LTHThio sedi. ICR	01 December 2019
1468000020	TSA w. Pen. LTHThio sedi. ICR+	01 December 2019
1468000120	TSA w. Pen. LTHThio sedi. ICR+	01 December 2019
1468030020	Veg. Pept.Agar w. LTHThio cont.-ICR+	01 August 2020
1468030200	Veg. Pept.Agar w. LTHThio cont.-ICR+	01 August 2020
1468040020	Veg. Pept.Agar w. LTHThio sedi.-ICR+	01 December 2019
1468040120	Veg. Pept.Agar w. LTHThio sedi.-ICR+	01 December 2019



Table 2: additional information related to the change in manufacturing site.

Change description	Transfer to existing manufacturing Facilities in Molsheim, France
Changes to clean room layout, process flow, or equipment?	Layout of clean rooms, process flow, and equipment are equivalent to existing production facility in Eppelheim.
Changes to manufacturing process?	<p>No change. Media production processes according to established standard operation procedures (SOPs) are maintained.</p> <p>Manufacturing lines in Molsheim (France) have been qualified for media preparation, filling and packaging of all types of ICR, ICRplus, LI and RT contact and settle plates since 2015.</p>
Changes to gamma irradiation procedures?	Gamma-irradiation parameters and irradiation levels will be equivalent to the current process.
Changes to quality control protocols and procedures?	Protocols and procedures for quality control are maintained according to established SOPs.
Identification of product manufactured at the new production site?	<p>No change to the number of digits used for batch identification.</p> <p>No change to the existing barcode sequencing.</p> <p>Lot numbers are automatically assigned by the production system assuring full lot traceability. Numbering is assigned randomly, based on 6 digits derived from the job number system.</p>
Changes in packaging and product labels?	<p>General processes for packaging and warehousing are maintained according to established SOPs.</p> <p>No change to the packaging materials' specifications.</p> <p>Minor changes might occur to the labelling and secondary packaging. Details will be communicated in a follow-up notification for the concerned products.</p>



Change description	Transfer to existing manufacturing Facilities in Molsheim, France
Changes to release testing procedures, specifications or validation?	No change. The same release criteria with same specifications are applied.
Differences between products manufactured at different sites?	Appearance: No Change Specifications: No change Performance: No change Raw materials: No change Shelf life: No change
Changes to Certificate of Analysis (CoA)?	Minor Changes reflecting the change of the production site only. No change to the download procedure.
Changes to storage temperature?	Product storage temperature ranges will be harmonized. The storage temperature range for products currently stored at 4-12°C will be lowered to 2-8°C.
Changes to distribution?	Products manufactured in Molsheim will be shipped either from Strasbourg, France or from usual warehouse.

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