# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire

Module 2, Site Specific Information and

Module 4, Warehouse & Distribution Appendix

Relevant for **Millipore SAS**
**39, Route Industrielle de la Hardt**
**67120 Molsheim,France**
**An affiliate of Merck KGaA, Darmstadt, Germany**

The site self-assessment covers our quality management system for the following regulated applications:

- Manufacturing of devices media and equipment for fluid analysis and purification and manufacturing of single use components and water purification systems
- warehousing and distribution

Rx 360 An International Pharmaceutical Supply Chain Consortium

Merck KGaA, Darmstadt, Germany is an active member of the Rx 360 Consortium.

As a trusted partner of our customers, we deliver quality - always.

Merck KGaA
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany

# Information

This document is based on the Rx-360 Consortium's Supplier Assessment Questionnaire template, Module 2 and Module 4. The contents of this questionnaire are built on the Rx-360 questionnaire version 2.0 intact with no question added or deleted.
Rx-360's CEO/COO gave permission to Life Science to use the Rx-360 logo.

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# Rx-360 Supplier Assessment Questionnaire : Site-Specific Information

☒ Please check here if additional documents are attached.

| SECTION 1. General Site Information | |
|---|---|
| 1.1 | Site or Facility-Specific Name:<br>Millipore SAS |
| 1.2 | Address:<br>Millipore SAS<br>39, Route Industrielle de la Hardt<br>67210 Molsheim<br>France<br><br>GPS Coordinates:<br>48.5418 Latitude ; 7.5297 Longitude |
| 1.3 | Phone:<br>+33 3 90 46 90 00 |
| 1.4 | Email:<br>Please contact your local Sales representative |
| 1.5 | Fax:<br>None |
| 1.6 | Website:<br>www.sigmaaldrich.com |

| SECTION 2. General Site Operating Information | |
|---|---|
| 2.1 | What year did the site start operating? 1972 |
| 2.2 | What is the primary activity of the site? (e.g. manufacturing, distribution, etc.)<br>Design, development, production engineering, planning, manufacturing and distribution of devices, equipment, media, for fluid analysis and purification.<br>Production engineering manufacturing and distribution of water purification systems for laboratories.<br>Manufacturing of single use components and delivery of engineered systems and technical solutions for fluid storage, filtration, and separation.<br>Scientific, commercial, technical and validation support to customers.<br>Maintenance and repair for biomonitoring and process solution equipment's |
| 2.3 | To which, if any, subdivision of the parent company does the site belong?<br>Merck KGaA, Darmstadt, Germany |
| 2.4 | Size of site (in sq. ft. or m.): 51487 m² |
| 2.5 | Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable):<br>Hours of Operation included between 7:00AM and 6:30PM.<br>Production Hours (product line / Operation depending):<br>a) 2X8: 6:00AM-02:00PM / 02:00PM-10:00PM<br>b) 5X8: 6:00AM-01:00PM / 01:00PM-08:00PM / 08:00PM-06:00AM<br>c) Night crew: 10:00PM-06:00AM<br>d) Week-end: 06:00AM-06:00PM<br>No shutdown. |
| 2.6 | Total number of employees on site:<br>~ 2285 |
| 2.7 | Total number of employees in Quality:<br>~ 200 |
| 2.8 | Total number of employees in Manufacturing:<br>~ 950 |
| 2.9 | What quality management system is utilized on site?<br>☒ ISO 9001<br>☐ ISO 13485<br>☐ 21 CFR Part 210/211 |

| SECTION 2. General Site Operating Information | | |
|---|---|---|
| | ☐ 21 CFR Part 820<br>☐ European GMP, Eudralex Volume 4 Part I<br>☐ European GMP, Eudralex Volume 4 Part II<br>☐ ICH Q7<br>☐ HACCP<br>☐ ISO 22000<br>☒ Other<br>Please describe: ISO14001, ISO17025 for BioM Quality Control Lab, ISO50001<br><br>Which Regulatory Initiatives does the site follow/comply with?<br>☒ REACH<br>☒ RoHs<br>☐ Ca Prop. 65<br>☒ WEEE | |
| 2.10 | Does the company/site have an export license? | ☒ Yes ☐ No ☐ N/A |
| 2.11 | Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)?<br>☐ Yes ☒ No ☐ N/A<br>If yes, please specify.<br>N/A | |
| 2.12 | By whom is the site inspected (regulatory or third party) and list inspections within the last three years:<br>DQS | |
| 2.13 | How often, as an annual average, is the site audited by customers or third parties?<br>~ 20 | |
| 2.14 | Has an Rx-360 audit been performed at this site? ☒ Yes ☐ No<br>Please also state the date of the audit if applicable.<br>3-5 may 2022<br>http://rx-360.org/audit-programs/ | |
| 2.15 | Are you willing to have Rx-360 conduct an audit on behalf of your customers according to the Rx-360 audit programs on your site?<br>☒ Yes ☐ No | |
| 2.16 | Are you willing to have your customers conduct audits on your site?<br>☒ Yes ☐ No | |

| SECTION 2. General Site Operating Information | | | | |
|---|---|---|---|---|
| 2.17 | Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.):<br>None | | | |
| 2.18 | Does the site outsource any quality-related activity?<br>☒ Yes ☐ No ☐ N/A<br>If answering yes, please specify the activities:<br>BioM: Testing, Sterilization<br>Systems & Solutions and Lab Water: Testing<br>Mobius:USP 788 Method 2 test | | | |
| 2.19 | Please check the supplier controls in place for this facility: | | | |
| 2.19a | Quality Agreements with Suppliers | ☒ Yes | ☐ No | ☐ N/A |
| 2.19b | Subcontractor Qualification/Audit Program | ☒ Yes | ☐ No | ☐ N/A |
| 2.19c | Periodic Review of Supplier Performance | ☒ Yes | ☐ No | ☐ N/A |
| 2.19d | Supplier Feedback Program | ☒ Yes | ☐ No | ☐ N/A |
| 2.19e | Approved Material Supplier List | ☒ Yes | ☐ No | ☐ N/A |
| 2.19f | Approved Service Supplier List | ☒ Yes | ☐ No | ☐ N/A |
| Additional comments:<br>2.10: For TFF Systems | | | | |

| SECTION 3. Objectionable Materials on Site | | | | |
|---|---|---|---|---|
| 3.1 | Does the site or production plant produce, process or store any of the following: | **Yes** | **No** | **Not Applicable** |
| 3.1a | Beta-Lactam Antibiotics | ☒ | ☐ | ☐ |
| 3.1b | Steroids and/or hormones | ☐ | ☒ | ☐ |
| 3.1c | High potency compounds | ☐ | ☒ | ☐ |
| 3.1d | Materials of animal origin/Biologics | ☒ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| 3.1e | Live virus or micro-organism | ☒ | ☐ | ☐ |
| 3.1f | Allergens | ☐ | ☒ | ☐ |
| 3.1g | Genetically Modified Organisms (GMO) | ☐ | ☒ | ☐ |
| 3.1h | Agrochemicals (Pesticides, Herbicides, Fungicides, etc.) | ☐ | ☒ | ☐ |
| 3.1i | Other (Please specify):<br>NA<br><br>Comment for 3.1a: Beta-lactam antibiotics are used as ingredient for a limited number of microbiological media. We have implemented measure to avoid cross contamination. | | | |

## SECTION 4. Cross Contamination Control

| 4.1 | Are any of the following cross-contamination controls in place? | **Yes** | **No** | **Not Applicable** |
|---|---|---|---|---|
| 4.1a | Dedicated Facilities | ☒ | ☐ | ☐ |
| 4.1b | Access Controls | ☒ | ☐ | ☐ |
| 4.1c | Dedicated Personnel | ☒ | ☐ | ☐ |
| 4.1d | Dedicated Gowning | ☒ | ☐ | ☐ |
| 4.1e | Procedural Controls | ☒ | ☐ | ☐ |
| 4.1f | Other (please specify): line clearance | | | |
| Additional Comments: NA | | | | |

## SECTION 5. Site Operating Policies

| 5.1 | Does the site utilize the following written policies, programs, or procedures? | | | |
|---|---|---|---|---|
| **Site Specific:** | | **Yes** | **No** | **Not Applicable** |
| 5.1a | Environmental, Health, and Safety | ☒ | ☐ | ☐ |
| 5.1b | Facility Environmental Control Policy | ☒ | ☐ | ☐ |
| 5.1c | General Facility Cleaning Procedures | ☒ | ☐ | ☐ |
| 5.1d | Hygiene and Sterilization Procedures | ☒ | ☐ | ☐ |
| 5.1e | Validated Equipment Cleaning Procedures | ☒ | ☐ | ☐ |
| 5.1f | Preventative Maintenance Program/Procedures | ☒ | ☐ | ☐ |
| 5.1g | Pest Control Program | ☒ | ☐ | ☐ |
| 5.1h | Master Production Procedure | ☒ | ☐ | ☐ |
| **Quality:** | | | | |
| 5.1i | Quality Control/Quality Management Policy | ☒ | ☐ | ☐ |
| 5.1j | Quality Manual | ☒ | ☐ | ☐ |
| 5.1k | Periodic Product Quality Review | ☒ | ☐ | ☐ |
| 5.1l | Master Validation Plan | ☒ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| 5.1m | Risk Assessment Program | ☒ | ☐ | ☐ |
| 5.1n | Supplier Approval Procedure | ☒ | ☐ | ☐ |
| 5.1o | Monitoring and Review of Approved Suppliers | ☒ | ☐ | ☐ |
| 5.1p | Mechanism to Reduce Testing | ☐ | ☒ | ☐ |
| 5.1q | Receiving Incoming Inspection | ☒ | ☐ | ☐ |
| 5.1r | Change Control Procedures | ☒ | ☐ | ☐ |
| 5.1s | Document Management Policy | ☒ | ☐ | ☐ |
| 5.1t | Document Retention Policy | ☒ | ☐ | ☐ |
| 5.1u | Change Notification Procedures for Clients | ☒ | ☐ | ☐ |
| 5.1v | Control of Nonconforming Material | ☒ | ☐ | ☐ |
| 5.1w | Deviation/Investigation Procedure | ☒ | ☐ | ☐ |
| 5.1x | Out of Specification Policy and Procedure | ☒ | ☐ | ☐ |
| 5.1y | Sampling Procedure/Sampling Plan | ☒ | ☐ | ☐ |
| 5.1z | Raw Material Retention Program | ☐ | ☒ | ☐ |
| 5.1aa | CAPA Procedure | ☒ | ☐ | ☐ |
| 5.1bb | Label Control and Accountability | ☒ | ☐ | ☐ |
| 5.1cc | Product Release Procedure | ☒ | ☐ | ☐ |
| 5.1dd | Employee Training Program | ☒ | ☐ | ☐ |
| 5.1ee | Stability, Expiration, and Shelf-Life Program | ☒ | ☐ | ☐ |
| 5.1ff | Product Retention Program | ☒ | ☐ | ☐ |
| 5.1gg | Recall Procedure | ☒ | ☐ | ☐ |
| 5.1hh | Customer Complaint Handling | ☒ | ☐ | ☐ |
| 5.1ii | Equipment validation/qualification procedure | ☒ | ☐ | ☐ |
| **SECTION 5. Site Operating Policies** | | | | |
| | | **Yes** | **No** | **Not Applicable** |
| 5.1jj | Internal audit/self-inspection program procedure | ☒ | ☐ | ☐ |
| 5.1kk | Site Security/Site Access Control Policies | ☒ | ☐ | ☐ |
| 5.1ll | New Hire Program/Induction Program | ☒ | ☐ | ☐ |
| **Business Continuity/Contingency Plan:** | | | | |
| 5.1mm | Disaster Recovery Plan | ☒ | ☐ | ☐ |
| 5.1nn | Pandemic Preparedness Plan | ☒ | ☐ | ☐ |
| 5.1oo | Supply Chain Emergency Preparedness Plan | ☒ | ☐ | ☐ |
| 5.1pp | Business Continuity/Contingency Plan | ☒ | ☐ | ☐ |
| 5.1qq | Can the company provide a plan upon request? OR provide a short description below:<br>It may be reviewed during an on-site audit after execution of our standard non-disclosure agreement. | | | |

| SECTION 6. Quality Assurance and Production | | | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 6.1 | Does the site have an independent and defined Quality Assurance/Quality Management Division? | ☒ | ☐ | ☐ |
| 6.2 | Does QA/QM have authority over the following: | | | |
| 6.2a | Policies and procedures? | ☒ | ☐ | ☐ |
| 6.2b | Review of documentation for release? | ☒ | ☐ | ☐ |
| 6.2c | Release or rejection of incoming materials? | ☒ | ☐ | ☐ |
| 6.3 | Does QA/QM investigate and resolve quality complaints? | ☒ | ☐ | ☐ |
| 6.4 | Does QA/QM investigate and resolve internal deviations? | ☒ | ☐ | ☐ |
| 6.5 | Does the QA/QM have the authority to assign a disposition to materials? | ☒ | ☐ | ☐ |
| 6.6 | Does the QA/QM review manufacturing and testing records prior to release? | ☒ | ☒ | ☐ |
| 6.7 | Does the facility utilize computerized systems for managing GxP activities or data? | ☐ | ☐ | ☒ |
| 6.8 | Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant? | ☐ | ☐ | ☒ |
| 6.9 | Does the site use statistical methods for consistency and uniformity? | ☒ | ☒ | ☒ |
| 6.10 | Does the site use controlled documents for following and recording manufacturing instructions? | ☒ | ☐ | ☐ |
| 6.11 | Does the company qualify and/or validate manufacturing procedures? | ☒ | ☐ | ☐ |
| 6.12 | Is any environmental monitoring conducted in production/finishing areas? | ☒ | ☐ | ☐ |
| 6.13 | Does the site supply BSE/TSE declarations? | ☒ | ☐ | ☒ |
| 6.14 | Does the site supply a declaration of Elemental Impurities? | ☐ | ☐ | ☒ |
| 6.15 | Are ICH Q3C solvents used in the manufacturing process of supplied materials? | ☐ | ☐ | ☒ |
| 6.15a | If Yes, what class of solvent is used? NA | | | |
| 6.16 | Are stability studies carried out according to ICH guidance? | ☐ | ☐ | ☒ |
| 6.17 | Are solvents and mother liquor reused/recycled? | ☐ | ☒ | ☐ |
| 6.18 | Does the site have a process water treatment system? | ☒ | ☐ | ☐ |

| SECTION 6. Quality Assurance and Production | | | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 6.18a | Please check all that apply to the system:<br>☒ City/potable water<br>☐ Distilled water<br>☐ Dionized water<br>☐ Water for injection (WFI)<br>☒ Reverse Osmosis<br>☒ Clean steam<br>☒ Ultra-filtrated water (purified water)<br>☒ Other: Mechanical Filtration, UV, water softener, Co2 degassing | | | |
| 6.19 | Does the plant have a batch/lot system? | ☒ | ☐ | ☐ |
| 6.19a | Is the system traceable? | ☒ | ☐ | ☐ |
| 6.19b | Is it unique? | ☒ | ☐ | ☐ |
| 6.19c | Is batch/lot manufacturing continuous? | ☐ | ☒ | ☐ |
| 6.19d | Is manufacturing batch by batch? | ☒ | ☐ | ☐ |
| 6.20 | Does the site perform on-plant audits prior to approving critical GxP suppliers? | ☐ | ☐ | ☒ |
| 6.21 | Does the site audit critical GxP suppliers after initial approval? | ☐ | ☐ | ☒ |
| 6.22 | Does the site inspect incoming materials? | ☒ | ☐ | ☐ |
| 6.23 | Does the site test incoming materials to defined specifications? | ☒ | ☐ | ☐ |
| 6.24 | Does the site establish purchase specifications for raw materials? | ☒ | ☐ | ☐ |
| 6.25 | Is the equipment multi-use? | ☒ | ☐ | ☐ |
| 6.26 | Does the site qualify equipment installation? | ☒ | ☐ | ☐ |
| 6.27 | Does the site qualify equipment operation? | ☒ | ☐ | ☐ |
| 6.28 | Does the site qualify equipment performance? | ☒ | ☐ | ☐ |
| 6.29 | Are production critical use instruments calibrated regularly? | ☒ | ☐ | ☐ |
| 6.30 | Is rework allowed? | ☒ | ☐ | ☐ |
| 6.31 | Is reprocessing allowed? | ☒ | ☐ | ☐ |
| 6.32 | Are manufacturing and packaging activities traceable to the equipment, areas, and materials used? | ☒ | ☐ | ☐ |
| 6.33 | Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination? | ☒ | ☐ | ☐ |
| 6.34 | If answering 'not applicable' for any of the above, please elaborate:<br>The site does not comply with GxP regulations.<br>Molsheim site has no GMP production, no drugs manufacturing | | | |
| Additional Comments: | | | | |

| SECTION 6. Quality Assurance and Production | | | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 6.6 No for Systems & Solutions Standard Hardware Products and Lab Water Operations<br>6.9 No for Systems & Solutions and Lab Water Operation / N/A for Mobius<br>6.13. N/A for Systems & Solutions for hardwares, LabWater Solutions & BioMonitoring Instruments.<br>6.30 / 6.31 Under specific requirements | | | | |

| SECTION 7. Laboratory Procedures | | ☐ N/A for this Site | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 7.1 | Does the site have standard procedures for sample handling/tracking? | ☒ | ☐ | ☐ |
| 7.1a | Does the site have standard procedures for retaining samples? | ☒ | ☒ | ☐ |
| 7.1b | Does the site have standard procedures for re-testing samples? | ☒ | ☐ | ☐ |
| 7.2 | Does the site have written and approved specifications and test methods? | ☒ | ☐ | ☐ |
| 7.3 | Are laboratory instruments calibrated regularly? | ☒ | ☐ | ☐ |
| 7.4 | Is there a standard procedure in place for analytical method development? | ☒ | ☐ | ☐ |
| 7.5 | Does the site qualify and/or validate analytical test procedures? | ☒ | ☐ | ☐ |
| 7.6 | Does the site perform stability testing on materials and/or products? | ☒ | ☐ | ☐ |
| 7.7 | Are retention samples of key raw materials maintained? | ☐ | ☒ | ☐ |
| 7.8 | Are standards traceable to their preparation and reagents used? | ☒ | ☐ | ☐ |
| 7.9 | Are retention samples of finished product maintained? | ☒ | ☐ | ☐ |
| 7.10 | Are shelf life/retest/expiration dates available and standardized? | ☒ | ☐ | ☐ |
| 7.11 | Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch? | ☒ | ☐ | ☐ |
| 7.12 | Does the CoA/CoC contain the manufacture name and location? | ☒ | ☐ | ☐ |
| 7.13 | Does the CoA/CoC signed/e-signed by a Quality representative? | ☒ | ☐ | ☐ |

| SECTION 7. Laboratory Procedures | | ☐ N/A for this Site | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 7.14 | If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data? | ☐ | ☐ | ☒ |
| 7.15 | If answering 'not applicable' for any of the above, please elaborate:<br>No repacking | | | |
| 7.16 | Additional Comments:<br>7.1a No for Mobius and Systems & Solutions Operation<br><br>7.11<br>Certificate of Conformity (CoC) is provided for Lab Water Operation.<br>Certificate of Quality (CoQ) are provided for other Operations and CoA are provided for some media products | | | |

| SECTION 8. Packaging, Storage, and Transport | | ☐ N/A for this Site | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 8.1 | Does the site have a validated or qualified labeling system? | ☒ | ☐ | ☐ |
| 8.2 | Are batch production records retained and available? | ☒ | ☐ | ☐ |
| 8.3 | Are packaging and labeling areas separate from production? | ☐ | ☒ | ☐ |
| 8.4 | Are barcode readers in use and challenged regularly? | ☒ | ☐ | ☐ |
| 8.5 | Are vision systems in use? | ☒ | ☒ | ☒ |
| 8.6 | Is product ever packaged without a label being initially applied (i.e. bright stocking)? | ☐ | ☒ | ☐ |
| 8.7 | Do labels include shelf life/expiration dates? | ☒ | ☐ | ☒ |
| 8.8 | Do labels include lot/batch number? | ☒ | ☐ | ☐ |
| 8.9 | Do labels include requirements for storage conditions? | ☒ | ☒ | ☐ |
| 8.10 | Is tamper evident seal used for each container of supplied materials? | ☒ | ☒ | ☐ |
| 8.11 | Does the company use a First-In-First-Out or First-Expiration-First-Out system? | ☒ | ☐ | ☐ |
| 8.12 | Does the company maintain appropriate storage conditions? | ☒ | ☐ | ☐ |
| 8.12a | Are those storage conditions monitored and documented? | ☒ | ☐ | ☐ |

| SECTION 8. Packaging, Storage, and Transport | | ☐ N/A for this Site | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **Not Applicable** |
| 8.13 | Does the site make available a description of storage and/or warehouse conditions? | ☒ | ☐ | ☐ |
| 8.14 | Does the site distribute products via a third party? | ☒ | ☐ | ☐ |
| 8.15 | Are good distribution policies implemented? | ☒ | ☐ | ☐ |
| 8.16 | Are transport mechanisms dedicated? | ☒ | ☐ | ☐ |
| 8.17 | Does the company validate shipping method? | ☒ | ☐ | ☐ |
| 8.18 | Does the company validate packaging methods? | ☒ | ☒ | ☐ |

Additional Comments:
8.3 for Mobius: Bags packaging and bags labeling in the assembly area
Cardboard box packaging and box labeling outside the assembly area
8.5 No for Systems & Solutions Operation and N/A for Mobius
8.7 No for Systems & Solutions Operation and LabWater Operation
8.9 No for Mobius
8.10 Tamper seals are used for Media fill bag / available for Hardware System in case of Customer request
8.18 if product requirement

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

Date:10/MAR/2023

Title:Quality Engineer

**Rx-360 Supplier Assessment Questionnaire**
**Module 4 : Service Supplier**
**Warehouse & Distribution Appendix**

☒ Please check here if additional documents are attached.

| SECTION 1. General Site Information | |
|---|---|
| 1.1 | Site or Facility-Specific Name:<br>Rhenus Logistics Alsace SAS |
| 1.2 | Address:<br>Warehouse SX1 : 9 rue de chalon 67000 Strasbourg<br>Warehouse SX2 : 11 rue du havre 67000 Strasbourg<br><br>GPS Coordinates (Map Coordinates/Longitude & Latitude):<br>Warehouse SX1 : 48°34'04.7"N 7°47'24.1"E<br>Warehouse SX2 : 48°33'41.7"N 7°47'17.8"E |
| 1.3 | Phone:<br>Please contact your local Sales representative |
| 1.4 | Email:<br>Please contact your local Sales representative |
| 1.5 | Fax:<br>/ |
| 1.6 | Website:<br>http://www.rhenus.group |
| 1.7 | If there is an individual contact for the following areas, please provide name and preferred contact information (at a minimum, name and telephone number or email):<br>Quality:<br>/<br>Technical Services:<br>/<br>Commercial/Business/Sales:<br>/<br>Primary Site Contact:<br>/ |

| Section 2. Warehousing, Distribution | | | | | ☐ N/A |
|---|---|---|---|---|---|
| 2.1 | Which of the following services are provided? (check all that apply)<br>☒ Warehousing<br>☒ Distribution<br>☐ Transportation | | | | |
| 2.2 | Does the company maintain specialized storage conditions? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.2 a | Does the site make available a description of storage and/or warehouse conditions? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.2 b | Are those storage conditions monitored and documented? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.3 | Does the company have policies or procedures that define the management and actions in response to storage condition excursions such as: | | | | |
| 2.3a | Investigation, root cause and CAPA for excursion? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.3b | Impact determination of excursion on stored items? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.3c | Notification to customers? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.4 | Does the company distribute products via a third party? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.5 | Are good distribution policies implemented? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.6 | Are transport mechanisms dedicated? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.7 | Does the company validate shipping methods? | ☒ Yes | ☐ No | ☐ N/A | |
| 2.8 | If answering ‘not applicable’ for any of the above, please elaborate:<br>/ | | | | |
| **Comments**<br>**(Please reference appropriate question number for any additional comments)** | | | | | |
| / | | | | | |

**I certify that the information is correct and verifiable.** ☒ Yes ☐ No

Date: 08 mars 2023

Title: EHS, Quality, Compliance & Service Providers Manager

## Additional Site-Specific Information (Molsheim)

## (not based on Rx 360 Supplier Assessment Questionnaire)

| **9. Warehouse and Distribution** | | | | |
|---|---|---|---|---|
| | | **Yes** | **No** | **N/A** |
| 9.1 | What is the scope of the Molsheim Distribution? | A Global distribution hub serving all Life Science business units & all geographies. Average of 14,400 items in inventory & 800,000 order lines shipped per year | | |
| 9.2 | How is it handled? | Logistics is operated by a Third-Party logistics supplier (3PL) | | |
| 9.3 | Do you have signed Contracts & agreements? | ☒ | ☐ | ☐ |
| 9.4 | Do you have a Service providers management in place' | ☒ | ☐ | ☐ |
| 9.5 | Do you audit your Service Providers? | ☒ | ☐ | ☐ |
| 9.6 | Where is it located? | 26,000 sqm dedicated to the company in Strasbourg, on a multi customers healthcare logistics campus | | |
| 9.7 | What standards do you have in place? | The distribution team is part of the company ISO 9001 certification Third Party logistics supplier is ISO 9001, 13485 (Medical Devices), 14001, Good Distribution Practices (GDP) certified & specific authorizations & licenses: GMO, AEO, ABP. A TQA (Technical Quality Agreement) is signed between our company and Rhenus. | | |

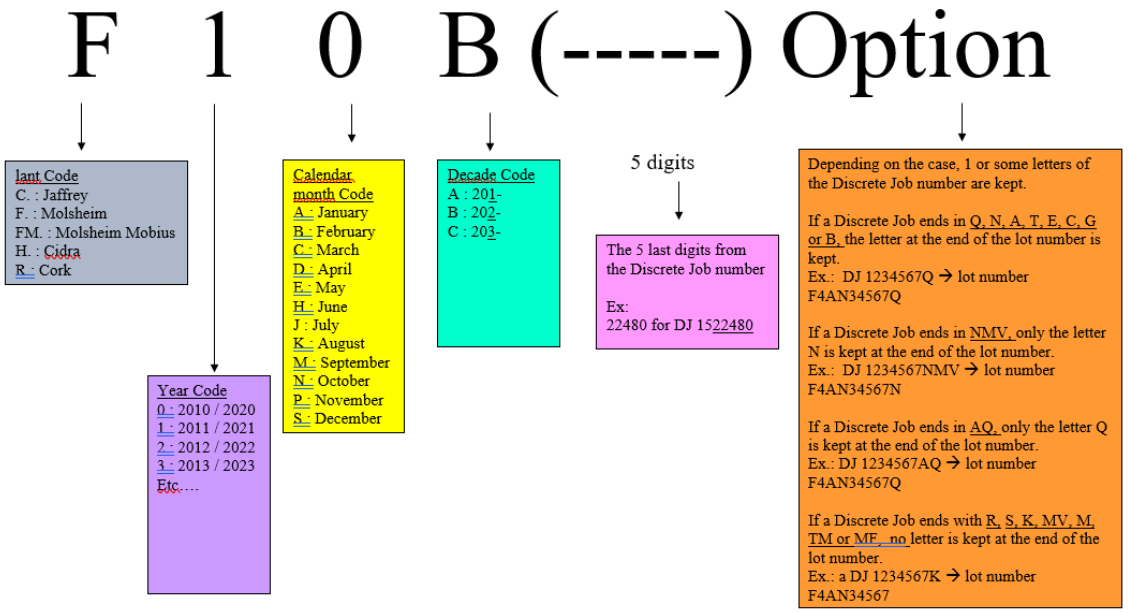
| | | |
|---|---|---|
| 9.8 | Do you have temperature-controlled areas? | We do have validated & temperature monitored storage areas, Ambient, 15-25°C, 2-8°C, -20°C, -80°C, -150°C & Liquid Nitrogen (-196°C) |
| 9.9 | Do you have alarms for temperature & hygrometry? | ☒ ☐ ☐ |
| 9.10 | How do you manage your inventory? | Daily cycle count |
| 9.11 | Do you have validated packaging? | ☒ specific shipments ☐ ☐ |
| 9.12 | How do you follow up your activity? | Daily operational follow up & monthly scorecards with management. One annual audit on site. |

# Additional Site-Specific Information

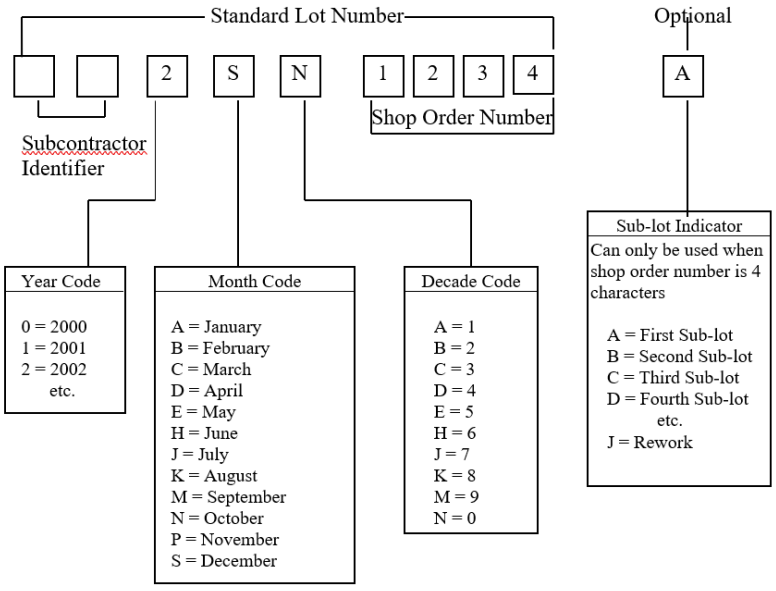
# (not based on Rx 360 Supplier Assessment Questionnaire)

## Lot numbering information

### For standard Millipore / Merck KGaA, Darmstadt, Germany products:




### Lot numbering for Lab Water parts subcontracted:



**For Novaseptum products:**
The lot number has the format YYMMDD-PXN, where

- YY represents the two last digits of the current year,
- MM represents the month's ordinal number,
- DD represents the day when the production of this lot was initiated.
- P defines production site that manufactured
- X is a code that may be used for special lot's, the default value is X=0.
- N defines in which order production was started on the day in question N=1, when only one manufacturing run is initiated on the day in question.

**For Contact plates and settle plates**

XXXXX 6 numbers
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.

**For Hycon contact slides and strips**

XXXXX 7 numbers
Lot numbers are automatically assigned by the production system assuring full lot traceability. Numbering is assigned randomly and corresponds to the job number system.

## Specific legal information for Molsheim plant-

## important for French customers

## (not based on Rx 360 Supplier Assessment Questionnaire)

| | |
|---|---|
| What is the SIRET code which is assigned to Molsheim Site by the "Institut national de la statistique et des études économiques (INSEE)" | 434 691 192 00018 |
| What is the SIREN code which is assigned to Molsheim Site by the "Institut national de la statistique et des études économiques (INSEE)" | 434 691 192 |
| What is the APE code (activité principale exercée), which is assigned by INSEE to any company and each of its establishments when it is registered in the SIRENE directory. | 2829B |