

## Certificate of Analysis

**Product Name:** Fetal Bovine Serum  
Heat Inactivated, USA No, sterile-filtered, cell culture

**Product Number:** F9665

**Batch Number:** BCCD0893

**Brand:** Sigma

**CAS Number:**

**Formula:**

**Formula Weight:**

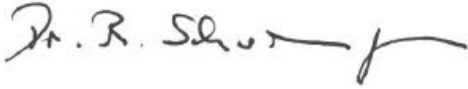
**Expiration Date:** FEB 2025

**Quality Release Date:** 01 APR 2020

<b>TEST</b>	<b>SPECIFICATION</b>	<b>RESULT</b>
<b>SOURCE</b>	NOT OF USA-ORIGIN	BRAZIL
<b>APPEARANCE</b>	CLEAR STRAW TO AMBER LIQUID	CLEAR STRAW TO AMBER LIQUID
<b>PH</b>	7 - 8	7.1
<b>OSMOLALITY</b>	260 - 340 MOSM/KG	314 MOSM/KG
<b>STERILITY</b>	PASS	PASS
<b>PROTEIN CONTENT</b>	30 - 45 G/L	41 G/L
<b>ENDOTOXINS</b>	≤ 10 EU/ML	< 0.4 EU/ML
<b>HAEMOGLOBIN</b>	≤ 25 MG/100ML	19 MG/ML
<b>MYCOPLASMA</b>	NOT DETECTED	NOT DETECTED
<b>VIRUS (BVD)</b>	TESTED	NOT DETECTED
<b>VIRUS (IBR, PI3)</b>	NOT DETECTED	NOT DETECTED
<b>CELL CULTURE TEST</b>	PASS	PASS
<b>CELL LINES</b>	REPORT CELL LINES USED	MRC5, L929, C2C12, LLC-PK1, VERO, SP2/O-AG14, MDCK
<b>CLONING ASSAY</b>	PASS	PASS
<b>ALBUMIN</b>	REPORT RESULT	16.3 G/L
<b>ALPHA GLOBULINS</b>	REPORT RESULT	13.9 G/L
<b>BETA GLOBULINS</b>	REPORT RESULT	6.7 G/L

## Certificate of Analysis

<b>GAMMA GLOBULINS</b>	REPORT RESULT	3.7 G/L
<b>IGG</b>	REPORT RESULT	206 MG/L



Dr. Reinhold Schwenninger  
Quality Assurance  
Buchs, Switzerland

Sigma-Aldrich warrants that at the time of the quality release or subsequent retest date this product conformed to the information contained in this publication. The current specification sheet may be available at Sigma-Aldrich.com. For further inquiries, please contact Technical Service. Purchaser must determine the suitability of the product for its particular use. See reverse side of invoice or packing slip for additional terms and conditions of sale.

# Certificate of Analysis



Cat.no. 11934317001  
Product RNA/DNA Stabil.-Reag.Blood/Bone Marrow

Lot 10966700  
29.07.2015  
Page 01 of 01

Parameter	Unit	Result
Appearance	-	yellowish solution
Performance	-	corresponds

This lot meets our specification.

Expiry date: Okt 2016  
Roche Diagnostics GmbH, Mannheim

sign.: Markus Pajatsch  
*Quality Manager*

This certificate is a computer printout and has therefore not been signed by hand.

3050 Spruce Street, Saint Louis, MO 63103, USA

Website: [www.sigmaaldrich.com](http://www.sigmaaldrich.com)

Email USA: [techserv@sial.com](mailto:techserv@sial.com)

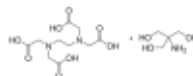
Outside USA: [eurtechserv@sial.com](mailto:eurtechserv@sial.com)

## Certificate of Analysis

Product Name:

Tris-EDTA buffer solution - 100X concentrate for Northern and Southern blotting

**Product Number:** T9285  
**Batch Number:** SLCG0161  
**Brand:** SIGMA  
**Quality Release Date:** 26 MAY 2020  
**Recommended Retest Date:** MAY 2023



Test	Specification	Result
Appearance (Color)	Colorless	Colorless
Appearance (Form)	Liquid	Liquid
Appearance (Turbidity)	Clear	Clear
pH	7.8 - 8.2	8.0
1x, H2O		
DNase, Exonuclease Detection	None Detected	None Detected
RNase Detection	None Detected	None Detected
Conductivity	≥ 30000	31110
Measured in umhos		
Standard Plate Count	≤ 10 CFU/ml	1 CFU/ml

Brian Dulle, Supervisor  
 Quality Assurance  
 St. Louis, Missouri US

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**Product Name:** Hydrochloric acid  
puriss. p.a., ACS reagent, reagent ISO, reagent Ph. Eur., fuming,  
≥ 37 %, APHA ≤ 10

**Product Number:** 30721

**Batch Number:** STBJ7931

**Brand:** Sigma-Aldrich

**CAS Number:** 7647-01-0

**Formula:** HCl

**Formula Weight:** 36.46

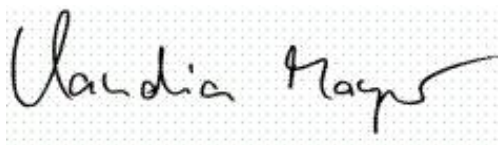
**Quality Release Date:** 29 MAY 2020

**Recommended Retest Date:** NOV 2023

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	COMPLYING	COLORLESS
APPEARANCE (FORM)	COMPLYING	LIQUID
COLOR (IN APHA)	≤ 10 APHA	< 10
ASSAY	≥ 37 %	37 %
DENSITY D20/4	≥ 1.18 G/ML	≥ 1.18 G/ML
RESIDUE ON IGNITION	≤ 0.0005 %	< 0.0002 %
RESIDUE (EVAPORATION)	≤ 0.005 %	< 0.005 %
FREE CHLORINE	≤ 0.00005 %	< 0.00005 %
ALUMINIUM	≤ 0.000005 %	< 0.000005 %
ARSEN	≤ 0.000001 %	< 0.000001 %
BARIUM	≤ 0.000002 %	< 0.000002 %
BERYLLIUM	≤ 0.000002 %	< 0.000002 %
BISMUTH	≤ 0.00001 %	< 0.00001 %
CALCIUM	≤ 0.00005 %	< 0.00005 %
CADMIUM	≤ 0.000001 %	< 0.000001 %
COBALT	≤ 0.000001 %	< 0.000001 %
CHROMIUM	≤ 0.000002 %	< 0.000002 %
COPPER	≤ 0.000002 %	< 0.000002 %
IRON	≤ 0.00002 %	< 0.00002 %
GERMANIUM	≤ 0.000005 %	< 0.000005 %
POTASSIUM	≤ 0.00001 %	< 0.00001 %
LITHIUM	≤ 0.000001 %	< 0.000001 %
MAGNESIUM	≤ 0.00001 %	< 0.00001 %
MANGANESE	≤ 0.000001 %	< 0.000001 %

## Certificate of Analysis

<b>MOLYBDENUM</b>	≤ 0.000002 %	< 0.000002 %
<b>SODIUM</b>	≤ 0.00005 %	< 0.00005 %
<b>NICKEL</b>	≤ 0.000002 %	< 0.000002 %
<b>LEAD</b>	≤ 0.000002 %	< 0.000002 %
<b>STRONTIUM</b>	≤ 0.000001 %	< 0.000001 %
<b>TITANIUM</b>	≤ 0.00001 %	< 0.00001 %
<b>THALLIUM</b>	≤ 0.000005 %	< 0.000005 %
<b>VANADIUM</b>	≤ 0.000001 %	< 0.000001 %
<b>ZINC</b>	≤ 0.000005 %	< 0.000005 %
<b>ZIRCONIUM</b>	≤ 0.00001 %	< 0.00001 %
<b>Heavy metals (by ICP-OES)</b>	≤ 0.0001 % (AS PB)	< 0.0001 %
<b>AMMONIUM (NH4+)</b>	≤ 0.0001 %	< 0.0001 %
<b>BROMIDE (BR)</b>	≤ 0.005 %	< 0.005 %
<b>PHOSPHATE (PO4)</b>	≤ 0.00005 %	< 0.00005 %
<b>SULFATE (SO4)</b>	≤ 0.0001 %	< 0.0001 %
<b>SULFITE (SO3)</b>	≤ 0.0001 %	< 0.0001 %



Claudia Mayer  
Manager Quality Control  
Steinheim, Germany

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THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

DQS Holding GmbH has issued an IQNet recognized certificate that the organization

## Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

### Scope:

Development, manufacture and distribution of basic chemicals, special chemical products and analytical systems.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

## ISO 9001 : 2015

Issued on: 2019-12-13  
Expires on: 2020-11-23

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration number: DE-005356 QM15

Alex Stoichitoiu  
President of IQNet

Michael Drechsel  
Managing Director of  
DQS Holding GmbH



### IQNet Partners\*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil  
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### **Location**

#### **Scope**

**005356**

**Merck KGaA  
Frankfurter Straße 250  
64293 Darmstadt**

Development, manufacture and distribution of basic chemicals, special chemical products and analytical systems.

**Including:  
Real Estate GmbH**

**Merck Performance Materials GmbH**

**With regional offices at:  
Roesslerstrasse 96  
64293 Darmstadt**

**Waldstrasse 3  
64331 Weiterstadt**

**519160**

**Merck S. A.  
Tronador 4890  
C1430DNN Buenos Aires  
Argentina**

Import, warehousing, trading and distribution of chemical products, lab equipment and IVD's.

**And regional warehouse at  
Marconi 877 – B1812CDE Carlos  
Spegazzini  
Pcia. de Buenos Aires  
Argentina**

**496580**

**Merck Pty. Limited  
885 Mountain Highway  
Bayswater VIC 3153  
Australia**

Distribution of chemicals, laboratory equipment and consumables, filtration, separation, Life Science and purification products.





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### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

<b>Location</b>	<b>Scope</b>
<b>531364</b> <b>Sigma-Aldrich Handels GmbH</b> <b>Marchettigasse 7 / 2</b> <b>1060 Vienna</b> <b>Austria</b>	Sales, customer and technical service for laboratory and industrial chemicals.
<b>531355</b> <b>Sigma-Aldrich BVBA SPRL</b> <b>Brusselsesteenweg 288</b> <b>3090 Overijse</b> <b>Belgium</b>	Sales, customer and technical service for laboratory and industrial chemicals.
<b>527487</b> <b>Merck Bulgaria EAD</b> <b>48 Sitnyakovo Blvd.</b> <b>1505 Sofia</b> <b>Bulgaria</b>	Sales and distribution of chemicals and reagents, raw materials, microbiological products, mixtures for analysis of foods, water and environment, chromatographic consumables, products used in laboratories and laboratory equipment. Service and maintenance. Training.
<b>541664</b> <b>Merck S.A. (Brazil)</b> <b>Alameda Xingu, 350, 5º andar - Alphaville</b> <b>Barueri</b> <b>06455-030</b> <b>Brazil</b>	Administrative process of importation and local purchase of finished products, equipment and raw materials for industries: pharmaceutical, chemical, food, beverages and research, development and analysis laboratory.



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### **Location**

#### **Scope**

**541662**

**Sigma Aldrich Brazil LTDA**  
**Alameda Xingu, 350, 5º andar - Alphaville**  
**Barueri**  
**06455-030**  
**Brazil**

Administrative process of importation and local purchase of finished products, equipment and raw materials for industries: pharmaceutical, chemical, food, beverages and research, development and analysis laboratory.

**541661**

**Merck S.A. (Brazil)**  
**Rua Torre Eiffel, 100**  
**Cotia - SP**  
**06705-481**  
**Brazil**

Importation, receiving, storage and distribution of finished products, equipment and raw materials for industries: pharmaceutical, chemical, food, beverages and research, development and analysis laboratory.

**527768**

**Sigma Aldrich Brazil LTDA**  
**Rua Torre Eiffel, 100**  
**Cotia - SP**  
**06705-481**  
**Brazil**

Importation, receiving, storage and distribution of finished products, equipment and raw materials for industries: pharmaceutical, chemical, food, beverages and research, development and analysis laboratory.

**527756**

**Sigma-Aldrich Canada Co.**  
**2149 Winston Park Drive**  
**Oakville L6H 6J8**  
**Canada**

Sales and distribution of biochemical and organic chemical products and kits.



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### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### Location

#### Scope

**450241**  
**Merck & Cie**  
**Weisshausmatte**  
**6460 Altdorf**  
**Switzerland**

Manufacture and distribution of active pharmaceutical ingredients, chromatography resins and other Life Science products.

**527490**  
**Sigma-Aldrich Chemie GmbH**  
**Industriestrasse 25**  
**9470 Buchs SG**  
**Switzerland**

Development, manufacturing and distribution of reagents and chemicals for research, development, production and analytical purposes.

**530377**  
**Sigma-Aldrich Production GmbH**  
**Industriestrasse 25**  
**9470 Buchs SG**  
**Switzerland**

Development, manufacturing and distribution of reagents and chemicals for research, development, production and analytical purposes.

**496582**  
**Merck S.A.**  
**Francisco de Paula Taforó 1981 - Ñuñoa**  
**7780349 Santiago**  
**Chile**

Distribution of chemical products and pharmaceutical ingredients, instruments and laboratory equipment.  
Service of installation, maintenance, repair and technical assist of instruments and equipment of laboratory.

**527755**  
**Sigma-Aldrich (Wuxi) Life Science & Technology Co., Ltd.**  
**99 Ximei Road**  
**Wuxi New District**  
**Wuxi City 214028**  
**P. R. China**

Packaging of bio-chemical reagent products (non-medicinal) and manufacture of disposal bio processing bags.



## Annex to IQNet Certificate Number: 005356 QM15

### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### Location

#### Scope

**519308**

**Merck Limited  
FLAT/RM 601-2, Li Po Chun Chambers,  
189 Des Voeux Road Central  
Hongkong  
P. R. China**

Sales, supply and innovation of Life Science chemical products and solutions.

**533161**

**Merck Life Science (Shanghai) Co. Ltd  
#10 Building, 509 Renqing Road  
Pudong District  
201201 Shanghai  
P. R. China**

Distribution and warehousing of Life Science chemicals.

**507106**

**Merck Life Science (Shanghai) Co. Ltd.  
(Sales Office)  
Room 908, Tomson-Trade Building,  
No.1 Jirong Rd,  
Waigaoqiao Free Trade Zone  
201203 Shanghai  
P. R. China**

Sales Office: Sales and supply of Life Science chemicals, materials, reagent, equipment and consumable.

China BioReliance Validation Services Lab:  
Provision of laboratory testing and validation service for filtration products and Single Use Assemblies.

System and Solutions Operations China:  
Design and provision of filtration and ultrafiltration products, system and related solution. Providing Consultancy Service in the areas of quality, regulatory affairs, audit management, training and validation.



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### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### Location

#### Scope

**514696**

**Merck Display Materials (Shanghai) Ltd.  
First Floor and Second Floor Area B of  
14th Building East Side and 15th building,  
No. 211 Qinqiao Road, Free Trade Zone  
201206 Shanghai  
P. R. China**

Design, development, manufacture and distribution of liquid crystal materials; distribution of other chemical materials.

**521709**

**Merck Electronic Materials (Suzhou) Ltd.  
Shanghai sales office  
First Floor and Second Floor Area B of  
14th Building East Side and 15th building,  
No. 211 Qinqiao Road,  
201206 Shanghai  
P. R. China**

Sale of photoresist products, edge bead rinse thinner and remover used for the electronic industry. Distribution of ancillary chemicals and additives used for electronic industry, including anti-reflective coating, developer and adhesion promoter.

**518298**

**Merck Electronic Materials (Suzhou) Ltd.  
No. 70, Longpu Road, Industrial Park  
215021 Suzhou City, Jiangsu Province  
P. R. China**

Production and sale of photoresist products, edge bead rinse thinner and remover used for electronic industry. Distribution of ancillary chemicals and additives used for electronic industry, including anti-reflective coating, developer and adhesion promoter.

**542618**

**Merck Life Science Technologies  
(Nantong) Co., Ltd  
No.39 Jianggang Road  
Nantong Economic & Technological  
Development Area  
226017 Jiangsu  
P.R. China**

Manufacturing of cell culture media, ready-to-use products and inorganic salts.



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Frankfurter Strasse 250  
64293 Darmstadt  
Germany

<b>Location</b>	<b>Scope</b>
<b>531357</b> <b>Sigma-Aldrich spol. s r.o.</b> <b>Na Hřebenech II 1718/10</b> <b>140 00 Praha 4</b> <b>Czech Republic</b>	Sales, customer and technical service for laboratory and industrial chemicals.
<b>092560</b> <b>Merck spol. s.r.o.</b> <b>Na Hřebenech II. 1718 / 10</b> <b>140 00 Praha 4</b> <b>Czech Republic</b>	Marketing, sales and distribution (including after sales service) of laboratory chemicals, instruments, equipment and consumables; chemicals for production; analytical systems.
<b>273047</b> <b>Biochrom GmbH</b> <b>Rahel-Hirsch-Str. 10</b> <b>10557 Berlin</b> <b>Germany</b>	Sales, customer and technical service for cell culture products and sterile liquids
<b>467000</b> <b>Litec-LLL GmbH</b> <b>Siemensallee 1</b> <b>Gebäude 67</b> <b>17489 Greifswald</b> <b>Germany</b>	Development and manufacture of phosphors.
<b>527728</b> <b>Sigma-Aldrich Biochemie GmbH</b> <b>Georg-Heyken-Strasse 14</b> <b>21147 Hamburg</b> <b>Germany</b>	Development, procurement, production, sales and distribution of reagents and chemicals for research, development, production and analytical purpose.



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### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

<b>Location</b>	<b>Scope</b>
<b>240237</b> <b>Merck KGaA</b> <b>Mainzer Strasse 41</b> <b>64579 Gernsheim</b> <b>Germany</b>	Development, manufacture and sales of chemical products.
<b>518299</b> <b>Merck Performance Materials GmbH</b> <b>Rheingastrasse 190 - 196</b> <b>65203 Wiesbaden</b> <b>Germany</b>	Design and development, production and supply of photoresist, liquid crystals and process chemicals for the electronic and printing industry.
<b>505611</b> <b>Merck Life Science GmbH</b> <b>Lilienthalstrasse 16</b> <b>69214 Eppelheim</b> <b>Germany</b>	Development, manufacture and distribution of culture media and systems for microbiology.
<b>531362</b> <b>Sigma-Aldrich Chemie GmbH</b> <b>Eschenstrasse 5</b> <b>82024 Taufkirchen</b> <b>Germany</b>	Sales, customer and technical service for laboratory and industrial chemicals.
<b>002955</b> <b>Merck Schuchardt OHG</b> <b>Eduard-Buchner-Strasse 14 - 20</b> <b>85662 Hohenbrunn</b> <b>Germany</b>	Manufacture, sales and distribution of chemicals for widespread applications in Pharma, Cosmetics and Technical Industry.

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### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

Location	Scope
<b>527503</b> <b>Sigma-Adrich Chemie GmbH</b> <b>Riedstrasse 2</b> <b>89555 Steinheim</b> <b>Germany</b>	Development, procurement, production and distribution of reagents and chemicals for research, development, production and analytical purpose.
<b>Incl. Sigma Aldrich Production GmbH</b> <b>Riedstrasse 2</b> <b>89555 Steinheim</b>	
<b>527729</b> <b>Sigma-Aldrich Chemie GmbH</b> <b>Kappelweg 1</b> <b>91625 Schnelldorf</b> <b>Germany</b>	Storage, packaging and shipping of chemicals.
<b>531349</b> <b>Sigma-Aldrich Denmark ApS</b> <b>Vandtårnsvej 62A, 5. A</b> <b>2860 Søborg</b> <b>Denmark</b>	Sales, customer excellence for laboratory and industrial chemicals.
<b>450321</b> <b>Merck S.L.U.</b> <b>Polígono Industrial Merck</b> <b>08100 Mollet del Valles (Barcelona)</b> <b>Spain</b>	Manufacture and distribution of chemicals for regulated markets and special applications.
<b>531363</b> <b>Sigma-Aldrich Química S.L.</b> <b>Calle de Maria de Molina, 40</b> <b>28006 Madrid</b> <b>Spain</b>	Sales, customer and technical service for laboratory and industrial chemicals.





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Frankfurter Strasse 250  
64293 Darmstadt  
Germany

Location	Scope
<b>531352</b> <b>Sigma-Aldrich Finland OY</b> <b>Keilaranta 6</b> <b>02150 Espoo</b> <b>Finland</b>	Sales, customer excellence for laboratory and industrial chemicals.
<b>527727</b> <b>Sigma-Aldrich Chimie S.a.r.l.</b> <b>80 Rue de Luzais</b> <b>38297 St. Quentin-Fallavier</b> <b>France</b>	Sales and distribution of reagents and chemicals for research, development and production.
<b>518302</b> <b>Merck Performance Materials SAS</b> <b>L'Usine de la Motte</b> <b>1 Rue du Flottage</b> <b>60350 Trosly Breuil</b> <b>France</b>	Design, manufacturing and distribution of colloidal silica.
<b>492648</b> <b>Millipore S.A.S.</b> <b>39, Route Industrielle de la Hardt</b> <b>67120 Molsheim</b> <b>France</b>	Design, development, production engineering, manufacturing and distribution of devices, media and equipment for fluid analysis and purification. Production engineering, manufacturing and distribution of water purification systems for laboratories. Deliver engineered systems and technical solutions. Validation and scientific support to users. Maintenance and repair for biomonitoring and process solution equipment. Technical and commercial support to customers.



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### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

<b>Location</b>	<b>Scope</b>
<b>534721</b> <b>Merck Chimie SAS</b> <b>10 Avenue de Lattre de Tassigny</b> <b>69330 Meyzieu</b> <b>France</b>	Development, production and sale of polymer microspheres mainly used as solid supports in diagnostic kits and marketed under the brand estapor.
<b>506585</b> <b>Millipore S.A.S.</b> <b>1, rue Jacques Monod</b> <b>Rond-Point des Sangliers</b> <b>78280 Guyancourt</b> <b>France</b>	Design, development of water purification systems for laboratories.
<b>527501</b> <b>Sigma-Aldrich Co. Ltd.</b> <b>Fancy Road</b> <b>Poole, Dorset</b> <b>BH12 4QH</b> <b>United Kingdom</b>	Sales of reagents and chemicals for research, development, production and analytical purposes.
<b>527761</b> <b>Sigma-Aldrich Co. Ltd.</b> <b>Homefield Road</b> <b>Haverhill, Suffolk</b> <b>CB9 8QP</b> <b>United Kingdom</b>	Manufacture of custom oligonucleotides. Sales and support of custom biomolecules and Life Science research products.
<b>505626</b> <b>Millipore (UK) Ltd.</b> <b>3 Fleming Road</b> <b>Kirkton Campus</b> <b>Livingston</b> <b>EH54 7BN</b> <b>United Kingdom</b>	Development, manufacture and sale of clinical diagnostic products derived from biological sources.



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Germany

<b>Location</b>	<b>Scope</b>
<b>527496</b> <b>Sigma-Aldrich Co. Ltd.</b> <b>T/A SAFC</b> <b>Second Avenue</b> <b>Heatherhouse Industrial Estate</b> <b>Irvine</b> <b>KA12 8NB</b> <b>United Kingdom</b>	Manufacture of cell culture related critical raw materials for the global health care industry.
<b>527730</b> <b>Sigma-Aldrich Co. Ltd.</b> <b>The Old Brickyard, New Road</b> <b>Gillingham, Dorset</b> <b>SP8 4XT</b> <b>United Kingdom</b>	Procurement, sales and distribution of reagents and chemicals for research, development, production and analytical purposes.
<b>501978</b> <b>Merck A.E. Hellas</b> <b>41-45 Kifissias ave.</b> <b>15123 Maroussi / Attica</b> <b>Greece</b>	Trade and distribution of pharmaceutical and chemical products and medical devices.
<b>505613</b> <b>Merck Kft.</b> <b>Október huszonharmadika utca 6 - 10</b> <b>1117 Budapest</b> <b>Hungary</b>	Distribution of laboratory and specialty chemicals and lab equipment. Servicing of distributed equipment.
<b>531351</b> <b>Sigma-Aldrich Kft.</b> <b>Október huszonharmadika utca 6 - 10</b> <b>1117 Budapest</b> <b>Hungary</b>	Sales, customer and technical service for laboratory and industrial chemicals.



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

<b>Location</b>	<b>Scope</b>
<b>450286</b> <b>P.T. Merck Tbk.</b> <b>Jl. TB. Simatupang no. 8</b> <b>Pasar Rebo</b> <b>Jakarta 13760</b> <b>Indonesia</b>	Sales, Marketing and Distribution of Pharmaceutical Raw Material Products.
<b>540290</b> <b>PT Merck Chemicals and Life Sciences</b> <b>Jl. TB. Simatupang No. 8</b> <b>Pasar Rebo</b> <b>Jakarta 13760</b> <b>Indonesia</b>	Sales, marketing and distribution of Life Science and Performance Material products.
<b>510831</b> <b>Merck Life Science Private Limited</b> <b>Godrej One, 8th floor, Pirojshanagar,</b> <b>Eastern Express Highway, Vikhroli - East</b> <b>Mumbai, Vikhroli 400 079</b> <b>India</b>	Development, manufacturing and marketing of microbiology products. Manufacturing and marketing of laboratory reagent. Marketing of laboratory products.
<b>518300</b> <b>Merck Performance Materials Pvt. Ltd.</b> <b>Khopoli Site</b> <b>Survey No 109, 110, 112 Savroli Village,</b> <b>Taluka Khalapur, Dist. Raigad</b> <b>Maharashtra 410 203</b> <b>India</b>	Design, development, manufacturing, marketing and sales of silicon resins (polysilazanes and silazanes) and formulations.



## Annex to IQNet Certificate Number: 005356 QM15

### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

Location	Scope
<p><b>501956</b> <b>Merck Life Science Private Limited</b> <b>50 A &amp; 51, 2nd Phase, Ring Road, Peenya</b> <b>Bangalore 560 058</b> <b>India</b></p> <p><b>And regional offices in New Delhi,</b> <b>Ahmedabad, Bangalore, Kolkata, Mumbai</b> <b>and Hyderabad</b></p>	<p>Design, manufacture, assembly, testing and supply of filtration equipment and related products for biopharm process solutions, biomonitoring, lab water, ASP (Analytical Sample Preparation), and provision of laboratory testing and validation service for filtration and single use products.</p>
<p><b>530393</b> <b>Sigma Aldrich Chemicals Private Limited</b> <b># 12, Bommasandra Jigani Link Road</b> <b>Bangalore, Karnataka State 560100</b> <b>India</b></p>	<p>Development, manufacturing, sales and distribution of specialty and fine chemicals.</p>
<p><b>505619</b> <b>Merck Millipore Ltd.</b> <b>Tullagreen</b> <b>Carrigtwohill</b> <b>T45 KD29 County Cork</b> <b>Ireland</b></p>	<p>Design and manufacture of filtration products for the pharmaceutical, food, beverage, electronic and analytical industries. Manufacture of chromatography adsorbents, immobilized enzymes and other ligands for modification and purification of biomolecules.</p>
<p><b>527495</b> <b>Sigma-Aldrich Ireland Ltd.</b> <b>Vale Road</b> <b>Arklow, County Wicklow</b> <b>Ireland</b></p>	<p>Procurement, sales and distribution of reagents and chemicals for research, development, production and analytical purposes.</p>



## Annex to IQNet Certificate Number: 005356 QM15

### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

Location	Scope
<b>527758</b> Sigma-Aldrich Israel Ltd. 3 Plaut St., Park Rabin Rehovot 7670603 Israel	Development, manufacture, marketing, sales and distribution of biochemicals, organic chemicals and reagents for research, production and analytical purposes.
<b>527759</b> Sigma-Aldrich Israel Ltd. 13-15 Kiryat Hamada St., Har Hotzvim Jerusalem 9777613 Israel	Development and manufacture of biochemicals, organic chemicals and reagents for research, development, production and analytical purposes.
<b>531353</b> Sigma-Aldrich S.r.l. Via Monterosa 93 20149 Milano Italy	Sales, customer and technical service for laboratory and industrial chemicals.
<b>518301</b> Merck Performance Materials Ltd. Shizuoka Site 3330 Chihama, Kakegawa-shi, Shizuoka 437-1412 Japan	Development and production of photoresists and other electronics materials related to chemical product, functional coating.
<b>527752</b> Sigma Aldrich Japan G.K. Ichikawa Site 368 O-Machi Ichikawa-Shi Chiba Japan	Manufacture and import sale of Custom Oligo DNA/RNA, custom Peptide and Antisera.



## Annex to IQNet Certificate Number: 005356 QM15

### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

Location	Scope
<b>532377</b> Merck Performance Materials Ltd. Atsugi Site 4084, Nakatsu, Aikawa-machi, Aiko-gun Kanagawa Pref. 243-0303 Japan	Design, development and manufacture of chemical products.
<b>497387</b> Merck Ltd. Atsugi Site 4084, Nakatsu, Aikawa-machi, Aiko-gun Kanagawa Pref. 243-0303 Japan	Distribution of Life Science products.
<b>532379</b> Merck Performance Materials Ltd. Arco Tower 5F, 1-8-1 Shimomeguro, Meguro-ku Tokyo 153-8927 Japan	Sales of chemical products.
<b>453292</b> Merck Ltd. Arco Tower 5F, 1-8-1 Shimomeguro, Meguro-ku Tokyo 153-8927 Japan	Supply chain and Quality for sales support of chemical products and life science products.



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

<b>Location</b>	<b>Scope</b>
<b>497388</b> Merck Ltd. Baraki Technical Center Nippon Express Baraki Air Cargo Center, 2526-26 Baraki Ichikawa, Chiba Pref. 272-0004 Japan	Stock holding and provision of repair for filtration products and analytical instrumentation.
<b>497390</b> Merck Ltd. Yokohama Technical Center YBP West Tower 2F, 134 Godo-cho, Hodogaya-ku Yokohama, Kanagawa Pref. 240-0005 Japan	Laboratory testing, validation and compliance services.
<b>With units</b> BioReliance Validation Services, Process solutions Life Science	
<b>426640</b> Merck Performance Materials Ltd. Onahama Site 51-15 Izumimachi Kurosuno Aza Egoshi Iwaki-shi, Fukushima 971-8184 Japan	Development and manufacture of chemical products.
<b>505622</b> Merck Performance Materials Ltd. 306, Pyeongtaekhang-Ro, Poseung-eup Pyeongtaek-shi, Gyeonggi-do 451-822 Republic of Korea	Development, manufacture, marketing, sales and servicing of chemicals.





## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

<b>Location</b>	<b>Scope</b>
<b>518304</b> <b>Merck Electronic Materials Ltd.</b> <b>50-14 Hyupdongdanji-gil, Miyang-myeon</b> <b>Anseong-si, Gyeonggi-do 17600</b> <b>Republic of Korea</b>	Research, development, production, inspection and testing of light-sensitive materials and related processing chemicals for semiconductor industry.
<b>505621</b> <b>Merck Ltd. Korea</b> <b>Haesung-Building 15F</b> <b>508 Teheran-ro, Gangnam-gu</b> <b>Seoul 06178</b> <b>Republic of Korea</b>	Marketing, sales and distribution of pharmaceuticals and chemical products including central functions (HR and finance administration).
<b>536979</b> <b>Sigma Aldrich Korea Ltd.</b> <b>113, Songdo Kukje-daero</b> <b>343 beon-gil Yeon-Su Gu,</b> <b>Incheon-City</b> <b>Republic of Korea</b>	Marketing, sales and distribution of reagents for research purposes.
<b>507107</b> <b>Merck S.A. de C.V.</b> <b>Calle 5 No. 7 Fracc. Ind. Alce Blanco</b> <b>53370 Naucalpan de Juárez</b> <b>Estado de México</b> <b>Mexico</b>	Sales, distribution and after sales of products and equipment of Life Science and Performance Materials business sectors.
<b>506583</b> <b>Merck Chemicals B.V.</b> <b>Haarlerbergweg 21 - 23</b> <b>1101 CH Amsterdam Zuidoost</b> <b>Netherlands</b>	Customer orders and cash processing.



## Annex to IQNet Certificate Number: 005356 QM15

### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

Location	Scope
<b>531365</b> <b>Sigma-Aldrich Chemie BV</b> <b>Stationsplein 4E</b> <b>3331 LL Zwijndrecht</b> <b>Netherlands</b>	Sales, customer and technical service for laboratory and industrial chemicals.
<b>531354</b> <b>Sigma-Aldrich Norway AS</b> <b>Drammensveien 123</b> <b>0277 Oslo</b> <b>Norway</b>	Sales, customer excellence for laboratory and industrial chemicals.
<b>506584</b> <b>Merck, Inc.</b> <b>24/F GT Tower International,</b> <b>6813 Ayala Avenue</b> <b>1227 Makati City, Metro Manila</b> <b>Philippines</b>	Marketing, sales and distribution of chemical products, laboratory supplies and equipment.
<b>531356</b> <b>Sigma-Aldrich Sp. z o. o., ul.</b> <b>Szelągowska 30</b> <b>61-626 Poznań</b> <b>Poland</b>	Sales, customer and technical service for laboratory and industrial chemicals.
<b>531358</b> <b>Sigma-Aldrich Química, S.L. Sucursal em</b> <b>Portugal</b> <b>Edifício DUO Miraflores, Alameda Fernão</b> <b>Lopes, 12 - 5A, B e 4B</b> <b>1495-190 Algés</b> <b>Portugal</b>	Sales of laboratory and industrial chemicals.



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### **Location**

#### **Scope**

**528833**

**Merck Romania SRL  
Str. Gara Herastrau 4D, Sector 2  
020334 Bucharest  
Romania**

Marketing and sales of specialty chemicals and high purity preparations, equipment analysis technology filtration equipment, installation and service of equipment sold. Storage of chemicals, medical devices and equipment.

#### **Warehouse**

**Localitatea Rudeni, Oras Chitila,  
Soseaua Rudeni nr. 74 A, Hala C2,  
077045 Judetul Ilfov  
Romania**

**496590**

**Merck Pte Ltd. (Life Science)  
2 Science Park Drive  
# 05-01/12 Ascent Building  
Singapore 118222  
Singapore**

Sales, marketing and distribution of chemicals, laboratory equipment and consumables, filtration, separation, Life Science and purification products.

**Warehouse: 5 Tuas Ave 3, #03-00  
Warehouse B  
Singapore 639405**

**540293**

**Sigma Aldrich Pte Ltd  
2 Science Park Drive  
#05-01/12 Ascent Building  
Singapore 118222  
Singapore**

Provision of warehouse related logistics services from goods receiving delivery to customers.

**Warehouse: 18 Tuas Loop**



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### **Location**

#### **Scope**

**527484**

**Merck d.o.o. Serbia  
Omladinskih brigada 90v  
11070 Belgrade  
Serbia**

Wholesale trade of medicines and medical devices.

**531348**

**Sigma-Aldrich spol. s r.o.  
Dvořákovo nábřežie 4  
810 06 Bratislava  
Slovakia**

Sales, customer and technical service for laboratory and industrial chemicals.

**531360**

**Sigma-Aldrich Sweden AB  
Solkraftsvägen 14C  
135 70 Stockholm  
Sweden**

Sales, customer and technical service and distribution of laboratory and industrial chemicals.

**527491**

**SAFC Hitech Taiwan Co., Ltd.  
No. 15, Luke 3rd Rd.  
Kaohsiung Science Park  
Luzhu Dist. 82151  
Kaohsiung City  
Taiwan**

Manufacture of chemicals for industrial applications (for optoelectronics and semiconductor devices).

**518305**

**Merck Performance Materials Ltd.  
No. 458-6, 8 & 11, Xinxing Rd.,  
Hu Kuo Township  
Hsinchu County  
Taiwan**

Development and manufacture of photo-resist products, top-layer anti-reflective coating materials and other chemical products.



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### **Location**

#### **Scope**

**426643**  
**Merck Performance Materials Ltd.**  
**No. 39, 39-1, Ching Chien 1st Road**  
**Kuan Yin Industrial Park**  
**Taoyuan**  
**Taiwan**

Development, manufacture and distribution of chemical products.

**542621**  
**Merck Ltd.**  
**6F, No.89,Sec.2, Tiding Blvd.,**  
**Taipei**  
**Taiwan**

Sales and distribution of Life Science Chemicals.

**505627**  
**EMD Millipore Corp.**  
**28820 Single Oak Drive**  
**Temecula, CA 92590**  
**United States of America**

Design and development, manufacture and distribution of chemical and biological reagents.

#### **With associated organization:**

**26578 Old Julian Highway**  
**Ramona, CA 92065**

**534975**  
**EMD Performance Materials - Ormet**  
**Circuits, Inc**  
**6555 Nancy Ridge Drive Suite 200**  
**San Diego, CA 92121**  
**United States of America**

The design, development and manufacture of conductive pastes, inks and other materials for electronic applications.



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### **Location**

#### **Scope**

**505631**  
**EMD Millipore Corp.**  
**28820 Single Oak Drive**  
**Temecula, CA 92590**  
**United States of America**

Design and development, manufacture, technical support and distribution of research use only immunoassay kits. Bioscience global technical and sales support organization.

**450330**  
**EMD Performance Materials Corp.**  
**110 EMD Blvd.**  
**Savannah, GA 31402**  
**United States of America**

Design and development, manufacture and distribution of pigments.

**496589**  
**EMD Millipore Corp.**  
**195 W. Birch Street**  
**Kankakee, IL 60901**  
**United States of America**

Design, development, manufacturing and distribution of highly purified blood proteins and biologically active factors.

**With associated organization:**

**2407 Eastgate Industrial Parkway**  
**Kanakee, IL 60901**

**527747**  
**Sigma-Aldrich**  
**1302 West Anthony Drive**  
**Urbana, IL 61802**  
**United States of America**

Manufacture of reagents and chemicals for research, development, production and analytical purposes.

**527749**  
**SAFC Biosciences, Inc.**  
**11296 Renner Boulevard**  
**Lenexa, KS 66215**  
**United States of America**

Design, control, procurement and distribution of sera and dry powder media.



## Annex to IQNet Certificate Number: 005356 QM15

### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

Location	Scope
<b>527748</b> <b>SAFC Biosciences, Inc.</b> <b>13804 West 107th Street</b> <b>Lenexa, KS 66215</b> <b>United States of America</b>	Design, control, procurement, manufacturing and distribution of sera, dry powder media, as well as repackaging of raw materials.
<b>496583</b> <b>EMD Millipore Corp.</b> <b>80 Ashby Road</b> <b>Bedford, MA 01730</b> <b>United States of America</b>	Development & customer support for purification and separation media for life science applications, expression technology cell culture products; Service & repair for instruments.
<b>496285</b> <b>EMD Millipore Corp.</b> <b>400 Summit Drive</b> <b>Burlington, MA 01803</b> <b>United States of America</b>	QA, supply chain, 3rd party finished goods, lab testing, validation & compliance service, design, development, manufacture of filtration equipment and chemical products.
<b>532231</b> <b>Sigma Aldrich Research Biochemicals, Inc. ("Sigma- RBI)</b> <b>600 Summit Drive</b> <b>Burlington, MA 01803</b> <b>United States of America</b>	Design, development, manufacturing, contract manufacturing of reagents, raw materials, components and kits.
<b>527489</b> <b>EMD Performance Materials Corp.</b> <b>1429 Hilldale Avenue</b> <b>Haverhill, MA 01832</b> <b>United States of America</b>	Manufacturing high purity chemicals for optoelectronics and semiconductor devices.



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

<b>Location</b>	<b>Scope</b>
<b>496587</b> <b>EMD Millipore Corp.</b> <b>17 Cherry Hill Drive</b> <b>Danvers, MA 01923</b> <b>United States of America</b>	Danvers single-use manufacturing.
<b>527745</b> <b>Sigma-Aldrich</b> <b>2425 South Second Street (Barton)</b> <b>St. Louis, MO 63104</b> <b>United States of America</b>	Storage and distribution of chemical reagents, raw materials, media, components and kits.
<b>527743</b> <b>Sigma-Aldrich Corporation</b> <b>3500 Dekalb Street</b> <b>St. Louis, MO 63118</b> <b>United States of America</b>	Design, development, manufacturing, testing, QA, warehouse, maintenance of chemical reagents, raw materials and components. Customer processes.
<b>With associated organizations:</b> <b>- 545 South Ewing Street, St. Louis, MO 63103</b> <b>- 3300 South Second Street, XY Building, St. Louis, MO 63118</b> <b>- 2909 Laclede Street, St. Louis, MO 63101</b> <b>- 3050 Spruce Street, St. Louis, MO 63103</b>	
<b>527744</b> <b>Sigma-Aldrich, Inc.</b> <b>3506 South Broadway (Broadway)</b> <b>St. Louis, MO 63118</b> <b>United States of America</b>	Design, development, customer processes, manufacturing, testing, QA, warehousing, maintenance of chemical reagents, raw materials and components.





## Annex to IQNet Certificate Number: 005356 QM15

### Merck KGaA

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

Location	Scope
<b>546398</b> Sigma-Aldrich, Inc. 3300 South Second Street St. Louis, MO 63118 (Cherokee) United States of America	Buffers: manufacturing, packaging, QA, QC
<b>546401</b> Sigma-Aldrich, Inc. 3506 South Broadway St. Louis, MO 63118 United States of America	Cell Culture Media: manufacturing, packaging, QA, QC
<b>492647</b> EMD Millipore Corp. 11 Prescott Road Jaffrey, NH 03452 United States of America	Manufacture of membrane and filtration products.
<b>518306</b> EMD Performance Materials Corp. 70 Meister Avenue Branchburg, NJ 08876 United States of America	Design and manufacture of photoresist and related chemical products.
<b>527764</b> Research Organics LLC., dba SAFC 4353 East 49th Street Cleveland, OH 44125 United States of America	Manufacturing of high purity biochemicals.



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### **Location**

#### **Scope**

**505606**

**EMD Millipore Corp.  
2828 Highland Avenue  
Norwood, OH 45212  
United States of America**

Design and development, manufacture and distribution of high purity organic solvents, organic chemicals/ reagents, acids and chemical specialities.

**527733**

**Sigma-Aldrich Corporation  
3858 Benner Road  
Miamisburg, OH 45342  
United States of America**

Development, procurement, production, testing and sales of chemicals, reagents and laboratory equipment for research, development, production and analytical purposes.

**527767**

**Supelco, Inc.  
595 North Harrison Rd.  
Bellefonte, PA 16823  
United States of America**

The design, development, manufacture, distribution and technical support of chromatography products for analysis and purification.

**527734**

**Aldrich Chemical Co., LLC  
Ironrun Industrial Park  
6950 Ambassador Drive  
Allentown, PA 18106  
United States of America**

Distribution of chemicals, reagents and laboratory equipment for research, development, production and analytical purposes.

**527751**

**SAFC Biosciences, Inc.  
5 Dutch Court (Reading)  
Sinking Spring, PA 19608  
United States of America**

Distribution of dry powder media and repackaging of raw materials.



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

<b>Location</b>	<b>Scope</b>
<b>518307</b> <b>EMD Performance Materials Corp.</b> <b>788 Chert Quarry Rd.</b> <b>Martin, SC 29836</b> <b>United States of America</b>	Design and manufacture of colloidal silica.
<b>With associated organization:</b>  <b>8604 Cliff Cameron Drive, Suite 105</b> <b>Charlotte, NC 28269</b> <b>United States of America</b>	
<b>527766</b> <b>Sigma-Genosys of Texas LLC</b> <b>Dbas Sigma Custom Products</b> <b>9186 Six Pines Drive, Suite 100</b> <b>The Woodlands, TX 77380</b> <b>United States of America</b>	Manufacture of DNA, siRNA, AQUA and PEPscreen peptides for the research and applied science markets.
<b>527762</b> <b>Cerilliant Corporation</b> <b>811 Paloma Drive, Suite A</b> <b>Round Rock, TX 78665</b> <b>United States of America</b>	Design and manufacturing of certified reference materials, analytical reference standards, analytes and chemical reagents.
<b>527738</b> <b>Aldrich Chemical Co., LLC</b> <b>6000 North Teutonia Avenue</b> <b>Milwaukee, WI 53209</b> <b>United States of America</b>	Development, procurement, production, testing, sales and distribution of chemicals, reagents and laboratory equipment for research, development, production and analytical purposes.
<b>With associated organizations at</b> <b>Milwaukee Emmber Lane, Sheboygan Falls</b> <b>and Port Washington.</b>	



## **Annex to IQNet Certificate Number: 005356 QM15**

### **Merck KGaA**

Frankfurter Strasse 250  
64293 Darmstadt  
Germany

#### **Location**

#### **Scope**

##### **527765**

**Sigma Aldrich RTC, Inc.  
2931 Soldier Springs Road  
Laramie, WY 82070  
United States of America**

Design, manufacturing, certify and distribute, certified reference materials and proficiency testing materials and to conduct laboratory proficiency testing program.

##### **505624**

**Merck (Pty) Ltd.  
Modderfontein & Wadeville  
1 Friesland Drive  
Longmeadow Business Estate  
Modderfontein 1645  
South Africa**

Sales, marketing and distribution of locally produced and imported goods for Life Science industry, pigments and cosmetics, and laboratory consumables.  
This includes installing, maintaining, repairing and validating Lab Water-, Bioscience-, Biomonitoring- and Third Party systems.

# Certificate

This is to certify that

**SIGMA-Aldrich Chemie GmbH**

91625 Schnelldorf

has introduced and applied a Management System for Occupational Health and Plant Safety, that complies with the requirements of the Occupational Health- and Risk-Management System -OHRIS:2010-.

This Management System also fulfills the "Guidelines on occupational safety and health management systems, ILO-OSH 2001", the "National Guidelines on Occupational Safety and Health Management Systems" as well as the LASI-Guidelines "Occupational Safety and Health Management Systems, LV 21".

Certificate No.

09 – 00260

This certificate is valid until

25.06.2020

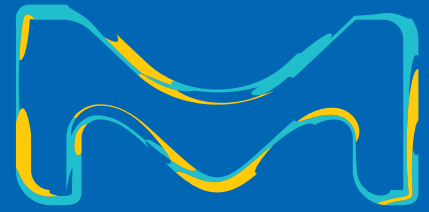
Ansbach, the 26.06.2017

by order of

Dr. Bauer  
District president



Bavarian State Ministry of  
Labour, Social and Family  
Affairs and Integration



# Site Quality Self-Assessment

based on

## Rx-360 Supplier Assessment Questionnaire Module 2, Site Specific Information

Relevant for

**Sigma-Aldrich Chemie GmbH**  
**Kappelweg 1**  
**91625 Schnelldorf**  
**Germany**

The site self-assessment covers our quality management system for the following applications:  
- central distribution center for Europe

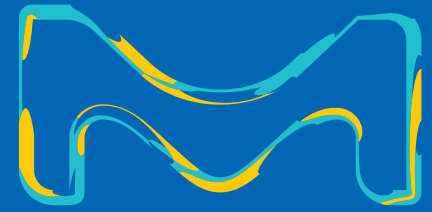


As a trusted partner of our customers, we deliver quality  
- always.

Merck KGaA, Darmstadt, Germany  
Corporation with General Partners  
Frankfurter Str. 250  
64293 Darmstadt, Germany  
Phone +49 6151 72-0

Sigma-Aldrich Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
3050 Spruce Street  
St. Louis, MO 63103, USA  
Phone +1 (800) 521-8956 / +1 (314) 771-5765

EMD Millipore Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
400 Summit Drive Burlington,  
MA 01803, USA  
Phone +1 (781) 533-6000



## Information

This document is based on the Rx-360 Consortium's Supplier Assessment Questionnaire template, Module 2. 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.



Merck KGaA, Darmstadt, Germany  
Corporation with General Partners  
Frankfurter Str. 250  
64293 Darmstadt, Germany  
Phone +49 6151 72-0

Sigma-Aldrich Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
3050 Spruce Street  
St. Louis, MO 63103, USA  
Phone +1 (800) 521-8956 / +1 (314) 771-5765

EMD Millipore Corporation  
A subsidiary of Merck KGaA, Darmstadt, Germany  
400 Summit Drive Burlington,  
MA 01803, USA  
Phone +1 (781) 533-6000

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

Please check here if additional documents are attached.

<b>SECTION 1. General Site Information</b>	
1.1	Site or Facility-Specific Name: Sigma-Aldrich Chemie GmbH Schnelldorf
1.2	Address: Kappelweg 1 91625 Schnelldorf  GPS Coordinates: Latitude 49°11'31.4874 Longitude 10°10'39.828
1.3	Phone: Phone: +49 (0)7950 9809 3065 24 h phone: +49 (0)9732 9972323
1.4	Email: please refer to your local Sales representative
1.5	Fax: + 49 (0)7950 9809 3005
1.6	Website: <a href="http://www.sigmaaldrich.com">www.sigmaaldrich.com</a>



<b>SECTION 2. General Site Operating Information</b>	
2.1	What year did the site start operating? 1998
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) The facility is operating as central distribution center for Europe. It is supplying distribution centers worldwide and is serving endcustomers in Europe and Middle East.
2.3	To which, if any, subdivision of the parent company does the site belong? Sigma-Aldrich Chemie GmbH, a subsidiary of Merck KGaA Darmstadt
2.4	Size of site (in sq. ft. or m.): 17400 sqm
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): Mo - Do, 7:00 - 22:00, Fr 7:00 - 20:00
2.6	Total number of employees on site: 220
2.7	Total number of employees in Quality: 1
2.8	Total number of employees in Manufacturing: 0
2.9	<p>What quality management system is utilized on site?</p> <p><input checked="" type="checkbox"/> ISO 9001  <input type="checkbox"/> ISO 13485  <input type="checkbox"/> 21 CFR Part 210/211  <input type="checkbox"/> 21 CFR Part 820  <input type="checkbox"/> European GMP, Eudralex Volume 4 Part I  <input type="checkbox"/> European GMP, Eudralex Volume 4 Part II  <input type="checkbox"/> ICH Q7  <input type="checkbox"/> HACCP  <input type="checkbox"/> ISO 22000  <input type="checkbox"/> Other</p> <p>Please describe:</p> <p>Which Regulatory Initiatives does the site follow/comply with?</p> <p><input checked="" type="checkbox"/> REACH</p>

<b>SECTION 2. General Site Operating Information</b>	
	<input type="checkbox"/> RoHs <input type="checkbox"/> Ca Prop. 65 <input type="checkbox"/> WEEE
2.10	Does the company/site have an export license? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.11	Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A If yes, please specify.
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: USP (2018) DQS (2018) Novo Nordisk (2018) Lonza (2016) Merck global quality functions (2017 and 2018)
2.13	How often, as an annual average, is the site audited by customers or third parties? 3
2.14	Has an Rx-360 audit been performed at this site? <input type="checkbox"/> Yes <input type="checkbox"/> No Please also state the date of the audit if applicable.  <a href="http://rx-360.org/audit-programs/">http://rx-360.org/audit-programs/</a>
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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
2.16	Are you willing to have your customers conduct audits on your site? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2.17	Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.): N/A
2.18	Does the site outsource any quality-related activity? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A If answering yes, please specify the activities:

<b>SECTION 2. General Site Operating Information</b>				
2.19	Please check the supplier controls in place for this facility:			
2.19a	Quality Agreements with Suppliers	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.19b	Subcontractor Qualification/Audit Program	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19c	Periodic Review of Supplier Performance	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19d	Supplier Feedback Program	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
2.19e	Approved Material Supplier List	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A
2.19f	Approved Service Supplier List	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Additional comments: Order, release and qualification of materials stored is not located on site. Quality agreements are in the responsibility of the releasing sites or appropriate marketing functions.				

<b>SECTION 3. Objectionable Materials on Site</b>				
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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1b	Steroids and/or hormones	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1c	High potency compounds	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1d	Materials of animal origin/Biologics	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1e	Live virus or micro-organism	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1f	Allergens	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1g	Genetically Modified Organisms (GMO)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1h	Agrochemicals (Pesticides, Herbicides, Fungicides, etc.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1i	Other (Please specify): Only storage of finished goods is performed at site. No bulk storage, no open product handling			
<b>SECTION 4. Cross Contamination Control</b>				

4.1	Are any of the following cross-contamination controls in place?	<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
4.1a	Dedicated Facilities	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1b	Access Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1c	Dedicated Personnel	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1d	Dedicated Gowning	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1e	Procedural Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1f	Other (please specify):			
Additional Comments: only closed containers are handled on site, no open product handling performed				

<b>SECTION 5. Site Operating Policies</b>				
5.1	Does the site utilize the following written policies, programs, or procedures?			
<b>Site Specific:</b>		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
5.1a	Environmental, Health, and Safety	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1b	Facility Environmental Control Policy	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1c	General Facility Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1d	Hygiene and Sterilization Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1e	Validated Equipment Cleaning Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1f	Preventative Maintenance Program/Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1g	Pest Control Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1h	Master Production Procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Quality:</b>				
5.1i	Quality Control/Quality Management Policy	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1j	Quality Manual	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1k	Periodic Product Quality Review	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1l	Master Validation Plan	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1m	Risk Assessment Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1n	Supplier Approval Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1o	Monitoring and Review of Approved Suppliers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1p	Mechanism to Reduce Testing	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1q	Receiving Incoming Inspection	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1r	Change Control Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1s	Document Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1t	Document Retention Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1u	Change Notification Procedures for Clients	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1v	Control of Nonconforming Material	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1w	Deviation/Investigation Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1x	Out of Specification Policy and Procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1y	Sampling Procedure/Sampling Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

5.1z	Raw Material Retention Program	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1aa	CAPA Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1bb	Label Control and Accountability	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1cc	Product Release Procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1dd	Employee Training Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ee	Stability, Expiration, and Shelf-Life Program	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1ff	Product Retention Program	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1gg	Recall Procedure	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5.1hh	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ii	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SECTION 5. Site Operating Policies</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
5.1jj	Internal audit/self-inspection program procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1kk	Site Security/Site Access Control Policies	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ll	New Hire Program/Induction Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Business Continuity/Contingency Plan:</b>				
5.1mm	Disaster Recovery Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1nn	Pandemic Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1oo	Supply Chain Emergency Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1pp	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1qq	Can the company provide a plan upon request? OR provide a short description below: Pandemic Preparedness Plan implemented in the OHRIS system. 5.1 mm, oo and pp are incorporated in the local Business Continuity Plan.			

<b>SECTION 6. Quality Assurance and Production</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
6.1	Does the site have an independent and defined Quality Assurance/Quality Management Division?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2	Does QA/QM have authority over the following:			
6.2a	Policies and procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2b	Review of documentation for release?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.2c	Release or rejection of incoming materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.3	Does QA/QM investigate and resolve quality complaints?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.4	Does QA/QM investigate and resolve internal deviations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5	Does the QA/QM have the authority to assign a disposition to materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

<b>SECTION 6. Quality Assurance and Production</b>				
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
6.6	Does the QA/QM review manufacturing and testing records prior to release?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.7	Does the facility utilize computerized systems for managing GxP activities or data?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.8	Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.9	Does the site use statistical methods for consistency and uniformity?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.10	Does the site use controlled documents for following and recording manufacturing instructions?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.11	Does the company qualify and/or validate manufacturing procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.12	Is any environmental monitoring conducted in production/finishing areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.13	Does the site supply BSE/TSE declarations?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.14	Does the site supply a declaration of Elemental Impurities?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.15	Are ICH Q3C(R4) solvents used in the manufacturing process of supplied materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.16	Are stability studies carried out according to ICH guidance?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.17	Are solvents and mother liquor reused/recycled?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.18	Does the site have a process water treatment system?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.18a	Please check all that apply to the system: <input type="checkbox"/> City/potable water <input type="checkbox"/> Distilled water <input type="checkbox"/> Dionized water <input type="checkbox"/> Water for injection (WFI) <input type="checkbox"/> Reverse Osmosis <input type="checkbox"/> Clean steam <input type="checkbox"/> Ultra-filtrated water (purified water) <input type="checkbox"/> Other:			
6.19	Does the plant have a batch/lot system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19a	Is the system traceable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19b	Is it unique?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19c	Is batch/lot manufacturing continuous?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.19d	Is manufacturing batch by batch?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.20	Does the site perform on-plant audits prior to approving critical GxP suppliers?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

<b>SECTION 6. Quality Assurance and Production</b>				
		Yes	No	Not Applicable
6.21	Does the site audit critical GxP suppliers after initial approval?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.22	Does the site inspect incoming materials?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.23	Does the site test incoming materials to defined specifications?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.24	Does the site establish purchase specifications for raw materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.25	Is the equipment multi-use?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.26	Does the site qualify equipment installation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.27	Does the site qualify equipment operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.28	Does the site qualify equipment performance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.29	Are production critical use instruments calibrated regularly?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.30	Is rework allowed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.31	Is reprocessing allowed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.32	Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.33	Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.34	If answering 'not applicable' for any of the above, please elaborate: No production or QC activities on site. The site is a pure distribution center.			
Additional Comments:				

<b>SECTION 7. Laboratory Procedures</b>		<input checked="" type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
7.1	Does the site have standard procedures for sample handling/tracking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1a	Does the site have standard procedures for retaining samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1b	Does the site have standard procedures for re-testing samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2	Does the site have written and approved specifications and test methods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3	Are laboratory instruments calibrated regularly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4	Is there a standard procedure in place for analytical method development?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.5	Does the site qualify and/or validate analytical test procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.6	Does the site perform stability testing on materials and/or products?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>SECTION 7. Laboratory Procedures</b>		<input checked="" type="checkbox"/> <b>N/A for this Site</b>		
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
7.7	Are retention samples of key raw materials maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.8	Are standards traceable to their preparation and reagents used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.9	Are retention samples of finished product maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.10	Are shelf life/retest/expiration dates available and standardized?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.11	Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.12	Does the CoA/CoC contain the manufacture name and location?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.13	Does the CoA/CoC signed/e-signed by a Quality representative?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.14	If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate:			
7.16	Additional Comments:			

<b>SECTION 8. Packaging, Storage, and Transport</b>		<input type="checkbox"/> <b>N/A for this Site</b>		
		<b>Yes</b>	<b>No</b>	<b>Not Applicable</b>
8.1	Does the site have a validated or qualified labeling system?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.2	Are batch production records retained and available?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.3	Are packaging and labeling areas separate from production?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.4	Are barcode readers in use and challenged regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.5	Are vision systems in use?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.6	Is product ever packaged without a label being initially applied (i.e. bright stocking)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.7	Do labels include shelf life/expiration dates?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.8	Do labels include lot/batch number?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.9	Do labels include requirements for storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



<b>SECTION 8. Packaging, Storage, and Transport</b>		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
8.10	Is tamper evident seal used for each container of supplied materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8.11	Does the company use a First-In-First-Out or First-Expiration-First-Out system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12	Does the company maintain appropriate storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12a	Are those storage conditions monitored and documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.13	Does the site make available a description of storage and/or warehouse conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.14	Does the site distribute products via a third party?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.15	Are good distribution policies implemented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.16	Are transport mechanisms dedicated?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.17	Does the company validate shipping method?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.18	Does the company validate packaging methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Comments: Primary packaging and labelling is not performed on site. Only released materials from other sites or approved 3 <sup>rd</sup> party suppliers are stored and distributed. No open product handling performed on site.				

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

Date:08 Feb. 2019

Title:Site Director