

Important Update on Sterilization Certificates from STERIS

Effective August 2024, the Isofield range of sterile products that are gamma irradiated will be furnished with a Certificate of Processing (COP) instead of a Certificate of Irradiation (COI). This change is due to a change in Steris' Operations Data Management System (ODMS). It is important to clarify that this upgrade has no impact on any existing performance qualifications of the products and therefore, there is no requirement for re-qualification.

We apologize for the short notice. While Isofield was unofficially advised by STERIS in April 2024 of the impending change, we did not receive the new format COP or actual implementation date confirmation until 30th July 2024.

This is a running change therefore there may be times you may receive products with COI and COP in the same shipment.

We have provided below explanations concerning changes to the document and label formats. The official notification from our sterilization service provider is also attached for your reference.



OLD: ISOFIELD – CERTIFICATE OF ANALYSIS



CERTIFICATE OF ANALYSIS

PRODUCT NAME	Isofield CR++
PRODUCT CODE / SIZE	1036060
LOT	240082
MANUFACTURING DATE	2024-02
EXPIRY DATE	2029-01
CERTIFICATE OF IRRADIATION	S1278230911

PROPERTY	TEST METHOD	TEST PLAN	RESULT
Pinholes – Water Tight Test	EN ISO 374-2	AQL 0.65; G1	Conforms
Visual – major defects	In-house	AQL 2.5; G1	Conforms
Visual – minor defects	In-house	AQL 4.0; G1	Conforms
Dimension	EN ISO 21420, EN 455-2	AQL 4.0; S2	Conforms
Physical Properties	EN455-2	AQL 4.0; S2	Conforms
Packing Configuration	In-house	NA	Conforms
Extractable Ionics	IEST-RP-CC005.4	N=3	Conforms
Liquid Particle Count	IEST-RP-CC005.4	N=3	Conforms
Sterilization	Gamma Irradiation	Minimum 25kGy	Conforms
Endotoxin	EN455-3, USP	≤20 EU/Pair	Conforms












COMPANY
ISOFIELD SDN. BHD.
(Registration No: 20190129008 (1246328-A))


NAME
Steve Morgan

DATE
6 March 2024

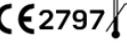
NEW: ISOFIELD – CERTIFICATE OF ANALYSIS



CERTIFICATE OF ANALYSIS

PRODUCT NAME	Isofield CR++
PRODUCT CODE / SIZE	1036060
LOT	240XYZ
MANUFACTURING DATE	2024-AA
EXPIRY DATE	2029-BB
CERTIFICATE OF PROCESSING	3043-1024A

PROPERTY	TEST METHOD	TEST PLAN	RESULT
Pinholes – Water Tight Test	EN ISO 374-2	AQL 0.65; G1	Conforms
Visual – major defects	In-house	AQL 2.5; G1	Conforms
Visual – minor defects	In-house	AQL 4.0; G1	Conforms
Dimension	EN ISO 21420, EN 455-2	AQL 4.0; S2	Conforms
Physical Properties	EN455-2	AQL 4.0; S2	Conforms
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COMPANY

NAME

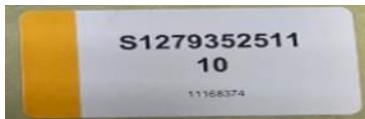
DATE

EXAMPLE

OLD – CERTIFICATE OF IRRADIATION

STERIS		11132657																																
 <p>http://www.steris-est.com</p> <p>Certificate of Irradiation</p> <p>Date Issued: 02-May-2024</p> <p>MY01SL2788514-1-1</p> <p>COI #</p>																																		
<p>This is to certify that Synergy Sterilisation Rawang (M) Sdn. Bhd., a STERIS company has where appropriate delivered an irradiation process in accordance with the current certified standards:</p> <p>EN ISO 11137-1 Sterilisation of Health Care Products ISO 9001 Quality Management System EN ISO 13485 Quality System - Medical Devices</p> <p>ISOFIELD SDN BHD NO. 6 JALAN GUDANG 16/9 SEKSYEN 16 SELANGOR 40200 SHAH ALAM</p>																																		
<p>Order Information</p> <table border="1"> <tr> <td>Account Number:</td> <td>143599</td> </tr> <tr> <td>Synergy Health Sales Part Reference:</td> <td>1137098</td> </tr> <tr> <td>Customer Reference Number:</td> <td>SD024030</td> </tr> <tr> <td>Product Description:</td> <td>ISOFIELD VOLTA CLEANROOM GLOVE</td> </tr> <tr> <td>Validation Reference:</td> <td>R220001 Rev.1</td> </tr> <tr> <td>Quantity Received:</td> <td>24</td> </tr> <tr> <td>Customer Minimum Specification kGy:</td> <td>25.0</td> </tr> <tr> <td>Customer Maximum Specification kGy:</td> <td>40.0</td> </tr> <tr> <td>Other Process Details:</td> <td>PACKING: 200pr/ctn</td> </tr> <tr> <td>PRODUCT CODE</td> <td>LOT NO</td> <td>QTY</td> </tr> <tr> <td>2053065</td> <td>240165</td> <td>24</td> </tr> </table> <p>Irradiation Data</p> <table border="1"> <tr> <td>Date and Time of Irradiation:</td> <td>01-May-2024 17:13</td> </tr> <tr> <td>Reference Dose Range kGy:</td> <td>29.8 - 29.9</td> </tr> <tr> <td>Calculated Minimum Dose kGy:</td> <td>28.2</td> </tr> <tr> <td>Calculated Maximum Dose kGy:</td> <td>31.7</td> </tr> </table> <p>Irradiation Release Authorised By Synergy Sterilisation Rawang (M) Sdn. Bhd, a STERIS company</p> <p>Processing Site: Lot 42 Jalan Industri 2/1, Rawang Integrated Industrial Park, Rawang, 48000 Phone No: +603 6099 9600 Registered Office: 170-09-01, Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang, MALAYSIA VAT Number: 000678280704 Page 1 of 1</p>			Account Number:	143599	Synergy Health Sales Part Reference:	1137098	Customer Reference Number:	SD024030	Product Description:	ISOFIELD VOLTA CLEANROOM GLOVE	Validation Reference:	R220001 Rev.1	Quantity Received:	24	Customer Minimum Specification kGy:	25.0	Customer Maximum Specification kGy:	40.0	Other Process Details:	PACKING: 200pr/ctn	PRODUCT CODE	LOT NO	QTY	2053065	240165	24	Date and Time of Irradiation:	01-May-2024 17:13	Reference Dose Range kGy:	29.8 - 29.9	Calculated Minimum Dose kGy:	28.2	Calculated Maximum Dose kGy:	31.7
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OLD: IRRADIATION STICKER ON EACH CARTON



NEW: CERTIFICATE OF PROCESSING

STERIS: Certificate Of Processing

Prepared For ISOFIELD SDN. BHD (10859)

Gamma Process Run ID 3043-1024A

Product Code	Lot Number	Quantity	UOM
ISOFIELD ABC	240XYZ	72	Case

Validation Reference Number: R240009 Rev.1

Processing Run Start Date 13-May-2024 10:17 AM

Processing Run End Date 13-May-2024 10:23 AM

Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	30.0
Reference Dose Range (kGy)	27.8 - 36.7	Calculated Max Dose (kGy)	35.1

Product meets Customer specifications; zero nonconformities occurred during this run.

Signature Manifest

Reviewed and E-Signed by: [Signature] (Senior Applications Analyst)

Date/Time: 13-May-2024 10:32 AM

Document Content Revision 1

EXAMPLE

Operating facility is in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485, ISO 9001 current version and is in alignment with EN/ISO 11137 current version.

Processing Location

Synergy Sterilisation Rawang (M) Sdn Bhd, a STERIS Company
Lot 42, Jalan Industri 2/1
Rawang Integrated Industrial Park
48000 Rawang, Selangor, Malaysia

NEW: PROCESSING STICKER ON EACH CARTON

