

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.













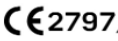


OLD: ISOFIELD – CERTIFICATE OF ANALYSIS



CERTIFICATE
OF ANALYSIS


PRODUCT NAME	Isofield CR++	PROPERTY	TEST METHOD	TEST PLAN	RESULT
PRODUCT CODE / SIZE	1036060	Pinholes – Water Tight Test	EN ISO 374-2	AQL 0.65; G1	Conforms
LOT	240082	Visual – major defects	In-house	AQL 2.5; G1	Conforms
MANUFACTURING DATE	2024-02	Visual – minor defects	In-house	AQL 4.0; G1	Conforms
EXPIRY DATE	2029-01	Dimension	EN ISO 21420, EN 455-2	AQL 4.0; S2	Conforms
CERTIFICATE OF IRRADIATION	S1278230911	Physical Properties	EN455-2	AQL 4.0; S2	Conforms
		Packing Configuration	In-house	NA	Conforms
		Extractable Ionics	IENT-RP-CC005.4	N=3	Conforms
		Liquid Particle Count	IENT-RP-CC005.4	N=3	Conforms
		Sterilization	Gamma Irradiation	Minimum 25kGy	Conforms
		Endotoxin	EN455-3, USP	≤20 EU/Pair	Conforms



COMPANY

NAME


DATE



Steve Morgan











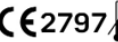
6 March 2024

NEW: ISOFIELD – CERTIFICATE OF ANALYSIS



CERTIFICATE
OF ANALYSIS

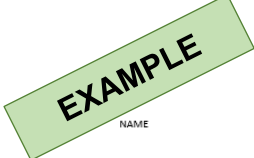
PRODUCT NAME	Isofield CR++	PROPERTY	TEST METHOD	TEST PLAN	RESULT
PRODUCT CODE / SIZE	1036060	Pinholes – Water Tight Test	EN ISO 374-2	AQL 0.65; G1	
LOT	240XYZ	Visual – major defects	In-house	AQL 2.5; G1	
MANUFACTURING DATE	2024-AA	Visual – minor defects	In-house	AQL 4.0; G1	
EXPIRY DATE	2029-BB	Dimension	EN ISO 21420, EN 455-2	AQL 4.0; S2	
CERTIFICATE OF PROCESSING	3043-1024A	Physical Properties	EN455-2	AQL 4.0; S2	
		Packing Configuration	In-house	NA	
		Extractable Ionics	IENT-RP-CC005.4	N=3	
		Liquid Particle Count	IENT-RP-CC005.4	N=3	
		Sterilization	Gamma Irradiation	Minimum 25kGy	
		Endotoxin	EN455-3, USP	≤20 EU/Pair	



COMPANY

NAME


DATE



EXAMPLE

OLD – CERTIFICATE OF IRRADIATION

11132057



http://www.steris-ast.com

Certificate of Irradiation

Date Issued: 02-May-2024

MY01512788514-1-1

COI #

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:

EN ISO 11137-1 Sterilisation of Health Care Products
ISO 9001 Quality Management System
EN ISO 13485 Quality System - Medical Devices

ISOFIELD SDN BHD
NO. 6 JALAN GUDANG 16/9
SEKSYEN 16
SELANGOR
40200 SHAH ALAM

Order Information

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: 200prs/ctn	
PRODUCT CODE	LOT NO QTY
2053065	240165 24

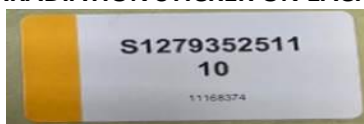
Irradiation Data

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

Irradiation Release Authorised By Synergy Sterilisation Rawang (M) Sdn. Bhd, a STERIS company

Processing Site: Lot 42 Jalan Industri 2/1, Rawang Integrated Industrial Park, Rawang, 48000 Phone No: +60(0)3 6099 9600
Registered Office: 170-09-01 Livingston Tower, Jalan Argyll, 10050 George Town, Pulau Pinang, MALAYSIA
VAT Number: 000678290704
Page 1 of 1

OLD: IRRADIATION STICKER ON EACH CARTON



NEW: CERTIFICATE OF PROCESSING

COP #

STERIS: Certificate Of Processing

Prepared For **ISOFIELD SDN. BHD (10859)**

Gamma Process Run ID **3043-1024A**

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

Signature Manifest

Reviewed and E-Signed by [Signature] (Senior Applications Analyst)
DateTime: 13-May-2024 10:32 AM
Document Content Revision 1

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

