

Important Update on Change to Certificate of Processing (COP)

Effective December 2025, the Isofield range of sterile products that undergo gamma or X-ray irradiation will be issued with a revised Certificate of Processing (COP).

This revision is driven by Steris' Operations Data Management System (ODMS) to promote uniformity, enhance operational efficiency and maintain compliance across all the global sterilization facilities.

The new COP format has been streamlined into a single page, replacing the previous two-page version. Previously, the second page was an attachment that listed product codes, lot numbers, and quantities. These details are now incorporated directly into the one-page certificate.

As this is a running change, there may be instances where shipments contain products accompanied by both the old and new COP formats. Both formats remain valid and compliant.

For clarity, we have outlined the specific changes to the document below.





OLD: ISOFIELD – CERTIFICATE OF PPROCESSING (2 Pages)

STERIS: Certificate Of Processing			
Prepared For	ISOFIELD SDN. BHD (10859)		
Gamma Process Run ID	3043-4024A		
Product Code	Lot Number	Quantity	UOM
ISOFIELD BLAZER LT CLEANROOM GLOVE	SEE ATTACHMENT	12	Case
Validation Reference Number: R220030 Rev.1			
Processing Run Start Date 11-Nov-2025 8:05 PM			
Processing Run End Date 12-Nov-2025 5:44 AM			
Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	28.0
Reference Dose Range (kGy)	27.2 - 34.5	Calculated Max Dose (kGy)	35.3
PO Number: N/A			
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.			
Signature Manifest			
Reviewed and E-Signed By: Kasmawati Kasim (Senior Quality Technician)			
DateTime Esigned 12-Nov-2025 11:18 AM			
Document Content Revision 1			
Operating facilities are 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 certified version, and is in alignment with EN ISO 11137 current certified 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			
Document ID: 17335			
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STERIS

Applied Sterilization Technologies

OTHER PROCESS DETAILS

GAMMA PROCESS RUN ID : 3043-4024A

PACKING : 200prs/ctn

PRODUCT CODE	LOT NO	QTY
1063070LT	250556LT	10
1063080LT	250656LT	2

NEW: ISOFIELD – CERTIFICATE OF PPROCESSING (1 Page)

STERIS: Certificate Of Processing			
Prepared For	ISOFIELD SDN. BHD (10859)		
Gamma Process Run ID	3043-4024A		
Product Code	Lot Number	Quantity	UOM
ISOFIELD BLAZER LT CLEANROOM GLOVE	SEE OTHER INFORMATION	12	Case
Validation Reference Number: R220030 Rev.1			
Processing Run Start Date 11-Nov-2025 8:05 PM			
Processing Run End Date 12-Nov-2025 5:44 AM			
Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	28.0
Reference Dose Range (kGy)	27.2 - 34.5	Calculated Max Dose (kGy)	35.3
PO Number: N/A			
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.			
Other Information			
ISOFIELD BLAZER LT CLEANROOM GLOVE Code:1063070LT, Lot:250556LT, Qty:10;			
Code:1063080LT, Lot:250656LT, Qty:2.			
Signature Manifest			
Reviewed and E-Signed By: Kasmawati Kasim (Senior Quality Technician)			
DateTime Esigned 12-Nov-2025 11:18 AM			
Document Content Revision 1			
Operating facilities are 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 certified version, and is in alignment with EN ISO 11137 current certified version.			
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