

CERTIFICATE OF ANALYSIS

PRODUCT NAME	Isofield CR++
PRODUCT CODE / SIZE	1036085
LOT	240579
MANUFACTURING DATE	2024-12
EXPIRY DATE	2029-11
CERTIFICATE OF IRRADIATION	3043-2399A

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	TEST-RP-CC005.4	N=3	Conforms
Liquid Particle Count	TEST-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: 201601039008 (1348338-A))
Authorized Signatory

NAME

Steve Morgan

DATE

3 Jan 2025

CERTIFICATE OF CONFORMANCE

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The above product is hereby declared to have been inspected and found to be in conformance with the agreed specifications as reported in the Certificate of Analysis.

STERIS: Certificate Of Processing

Prepared For ISOFIELD SDN. BHD (10859)
Gamma Process Run ID 3043-2399A

Product Code	Lot Number	Quantity	UOM
ISOFIELD CR++ CLEANROOM GLOVE	SEE ATTACHMENT	420	Case
Validation Reference Number: R220002 Rev.1			

Processing Run Start Date 31-Dec-2024 9:01 PM

Processing Run End Date 01-Jan-2025 7:05 AM

Specified Dose Range (kGy)	25.0 - 40.0	Calculated Min Dose (kGy)	27.7
Reference Dose Range (kGy)	26.9 - 36.2	Calculated Max Dose (kGy)	35.1

PO Number: N/A

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

Signature Manifest

Reviewed and E-Signed By: **Siti Nurbazilah Bahtiar (Senior Executive QA)**

DateTime Esigned 02-Jan-2025 10:33 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



Applied Sterilization Technologies

OTHER PROCESS DETAILS

GAMMA PROCESS RUN ID : 3043-2399A

PACKING : 100prs/ctn

PRODUCT CODE	LOT NO	QTY
1036080	240575	92
1036085	240579	61
1036060	240582	48
1036075	240578	60
1036090	240583	75
1036065	240576	84

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