

In line with Isofield's mission of continuous product improvement, we are happy to advise that we have included endotoxin testing for all our cleanroom gloves. This testing regime is part of our process control plan to ensure that our gloves are biologically safe and conform to BS EN 455-3:2015 and USP requirements.


To further provide a level of confidence in our gloves, we report the results of the endotoxin test in our Certificate of Analysis (COA). This came into effect from Lot # 230041, starting with Isofield LS300, Product Code: 10230, Size L, and applied to all cleanroom gloves manufactured subsequently. The change in our COA to reflect the endotoxin result is explained below.



7-March-2024

Change of COA

BEFORE



CERTIFICATE OF ANALYSIS

PROPERTY	TEST METHOD	TEST PLAN	RESULT
Pinholes – Water Tight Test	EN ISO 374-2	AQL 1.5; 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	NA

PRODUCT NAME Isofield LS300

PRODUCT CODE / SIZE 10230 / M

LOT 230040

MANUFACTURING DATE 2023-02


EXPIRY DATE 2026-01

CERTIFICATE OF IRRADIATION NA


COMPANY
ISOFIELD SDN BHD
Registered in Malaysia (1348338-A)

NAME
Steve Morgan

DATE
15 Feb 2023



AFTER



CERTIFICATE OF ANALYSIS

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

PRODUCT NAME Isofield VOLTA

PRODUCT CODE / SIZE 2053065

LOT 240001

MANUFACTURING DATE 2024-01


EXPIRY DATE 2026-12

CERTIFICATE OF IRRADIATION S1277820011

COMPANY
ISOFIELD SDN BHD
Registered in Malaysia (1348338-A)

NAME
Steve Morgan

DATE
1 Feb 24



Impacted Product Name & Product Code (as of 7-March-2024)

Product Name	Product Code
Isofield CR+	10040
Isofield LS400	10140
Isofield LS300	10230
Isofield CR++	10360
Isofield LS530	10553
Isofield Blazer	10630
Isofield Blazer LT	10630LT
Isofield NS300	20130
Isofield CRN+	20240
Isofield NS400	20340
Isofield Eclipse	20440
Isofield Volta	20530