

## CERTIFICATE OF CONFORMANCE

Product Description : SMARTLine™ Sterile Latex 400 DI

Certificate Number : 201178

Lot number : 25D59T84263A      Lot size : 204 cases

Manufacturing Date : April 2025      Expiry date : March 2030

### Product Details

Catalogue numbers	20 451	20 452	20 453	20 454	20 455	20 456
Sizes	6/XS	7/S	8/M	9/L	10/XL	11/XXL

### Physical Test Data

	Dimensions	Barrier Defects	Minor Defects	Major Defects
Sample size	13	125	125	125
AQL Level	4.0	1.0	2.5	1.5
Defects allowed	1	3	7	5
Defects found	0	0	1	3
Pass/Fail	Pass	Pass	Pass	Pass

Test method: EN ISO 374-2:2019 / EN 455-2:2024

### Physical Strength Properties Test

	BEFORE AGING	AFTER AGING
Sample Size	13	13
Force at Break (N) Median	14.7	12.9
Specification (N)	≥ 6.0	≥ 6.0
Pass/Fail	Pass	Pass

Test method: EN 455-2:2024

### Residual Powder Test

Size	8/M
Test Results, mg/glove	0.6
Specification, mg/glove	≤ 2.0
Pass/Fail	Pass

Test method: ASTM D6124-06 (2022)

### Particle Test Data

Particle size in $\mu\text{m}$	Average particles/ $\text{cm}^2$
0.5 – 1.0	1883
1.0 – 2.0	173
2.0 – 5.0	87
5.0 – 10.0	17
10.0 – 20.0	4
> 20.0	0
TOTAL per Sample	2164
Specification (Particles/ $\text{cm}^2 \geq 0.5\mu\text{m}$ )	< 3000

Test method: IEST-RP-CC005.4

**Extractable Test Data**

		Specification µg/cm <sup>2</sup>	Test Results µg/cm <sup>2</sup>
Ammonium	NH <sub>4</sub>	0.300	0.042
Bromide	Br	0.150	<0.008
Calcium	Ca	1.500	0.978
Chloride	Cl	0.600	0.345
Fluoride	F	0.030	<0.008
Magnesium	Mg	0.030	<0.008
Nitrate	NO <sub>3</sub>	1.200	0.523
Nitrite	NO <sub>2</sub>	0.300	<0.008
Potassium	K	0.150	0.033
Phosphate	PO <sub>4</sub>	0.150	<0.008
Sodium	Na	0.150	0.027
Sulphate	SO <sub>4</sub>	0.150	0.031

Test method: IEST-RP-CC005.4

**Non-Volatile Residue Test Data**

	Specification µg/cm <sup>2</sup>	Test Results µg/cm <sup>2</sup>
NVR	< 25	16.8

Test method: IEST-RP-CC005.4

**Endotoxin Data**

<20 Endotoxin Units/pair of Gloves (EN455-3:2023)

Test method: Limulus Amoebocyte Lysate kinetic chromogenic test

Detection limit: 0.1 EU/pair

Approved by:



Rubini Devi  
QA Manager

## CERTIFICATE OF IRRADIATION

Product Description : SMARTLine™ Sterile Latex 400 DI  
 Lot number : 25D59T84263A  
 Manufacturing Date : April 2025  
 Expiry Date : March 2030

Certificate Number : 100975  
 Irradiation Lot : 25061802  
 Irradiation Date : 13.06.2025

Product Details				
Lot Number	Product description	Catalogue Number	Size	Quantity in cases
25D59T84263A	SMARTLine™ Sterile Latex 400 DI	20 451	6 / Extra-Small	6
25D59T84263A	SMARTLine™ Sterile Latex 400 DI	20 452	7 / Small	25
25D59T84263A	SMARTLine™ Sterile Latex 400 DI	20 453	8 / Medium	55
25D59T84263A	SMARTLine™ Sterile Latex 400 DI	20 454	9 / Large	95
25D59T84263A	SMARTLine™ Sterile Latex 400 DI	20 455	10 / Extra-Large	15
25D59T84263A	SMARTLine™ Sterile Latex 400 DI	20 456	11 / Extra Extra-Large	8
TOTAL				204

Irradiation Facility Information*	
Irradiation Facility	Irradiation Method
Grand Ten Holdings Sdn Bhd, Plot PT 5754, Jalan 2, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor, Malaysia	Gamma Irradiation

\*Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10<sup>-6</sup>, in accordance with guidelines detailed in EN ISO 11137-2:2015 "Sterilization of Healthcare Products - Radiation"

Irradiation Dose Information**		
Dose Requested Minimum	Dose Delivered Minimum	Dose Delivered Maximum
25.0 kGy	30.7 kGy	38.5 kGy

\*\*Grand Ten Holdings Sdn Bhd has confirmed that the products have successfully been irradiated and have received the minimum dose requested (as the above stated) within the precision and accuracy of the dosimetry system employed.

Approved by:



Rubini Devi  
QA Manager