



Isofield Tera 230

Validated Sterile Tie-On Cleanroom Facemask

Last updated 25 Mar 2024

PRODUCT CODE	REF 60131	
	SIZE UNIVERSAL	

PRODUCT INFO

Validated sterile tie-on Cleanroom facemask
230mm length with a malleable nose strip, providing a secure fit and full face coverage
3-layer non-woven configuration
Highly efficient bacterial and particle filtration
Gamma irradiation, minimum 25kGy
Sterility Assurance Level 10⁻⁶
Particle Shedding (Helmke Drum) Category I
IPA resistant ink pouches to maintain traceability

CLEANROOM COMPATIBILITY

GMP Grade A cleanroom
GMP Grade B cleanroom
ISO Class 4 cleanroom
ISO Class 5 cleanroom
Class 10 cleanroom
Class 100 cleanroom

QUALITY ASSURANCE

Manufactured in a facility operating under an ISO 9001:2015 quality management system
Processed in a NEBB certified ISO Class 5 cleanroom

APPLICATIONS

Loading vials into a sterile lyophilizer
Aseptic filling, sealing, transfer of stoppered vials
Blending granulates and powders

STORAGE & SHELF LIFE

Store in a cool, dry place (< 40°C) away from direct sunlight
Do not expose open cartons to prolonged direct fluorescent light
Five (5) years from date of manufacture

PACKAGING

1 piece per sealed inner PE bag,
50 inner bags per sealed outer PE bag,
10 outer bags per lined carton (500 pieces)

PHYSICAL PROPERTIES

LENGTH	WIDTH	COLOUR	STYLE
230mm (± 5mm)	95mm (± 5mm)	White	Tie-On

MATERIALS

Outer layer	Non-woven spunbond polyester
Filtration Layer	Non-woven meltblown polyester
Inner facing layer	Non-woven polypropylene / polyethylene
Tie-tapes	Non-woven polyester

FILTRATION PROPERTIES

Particle Filtration Efficiency (PFE) @ 0.1 Micron	94%
Bacterial Filtration Efficiency (BFE) @ 0.3 Micron	97%
Differential Pressure (ΔP), mm H ₂ O/cm ²	6.8



TECHNICAL PROPERTIES

NORM	TEST REFERENCE	EXPLANATION
Sterility Validation Test	EN ISO 11137 Part 2:2015	Specifies requirements for the development, validation and routine control of a radiation sterilization process
Particle Generation Test by Helmke Drum	IEST-RP-CC003.4	Specifies methods for particle shed analysis in Helmke Drum applications

HELMKE DRUM TEST RESULT

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION	CLASS
≥ 0.3µm	84	less than 2000	1
≥ 0.5µm	33	less than 1200	1

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	4.32kg	4.32kg
Carton size	W29.5 L47 H21cm	W29.5 L47 H21cm
Nett weight	2.52kg	2.52kg
Air freight pallet	Max height: 141cm Layers: 6 Cartons: 34	Max height: 141cm Layers: 6 Cartons: 42
Sea freight pallet	Max height: 162cm Layers: 7 Cartons: 40	Max height: 162cm Layers: 7 Cartons: 49

DOCUMENTATION



CERTIFICATE OF CONFORMANCE (COC)
CERTIFICATE OF ANALYSIS (COA)
CERTIFICATE OF IRRADIATION (COI)

View [sample](#) of COC, COA, COI



FACTORY RELATED CERTIFICATIONS
To request ISO9001 Certificate,
please [email us](#)



Country of origin: **China**
HS Code: 6307909000

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