

HandSafe® GSNE100

Sterile Nitrile Examination Gloves

Powder Free Nitrile Examination Gloves, Sterile, Accelerator Free.

Gloves Specification:

- Nitrile
- Textured
- Indigo
- Beaded cuff For added strength and easier donning
- Sterile
- Strong, soft and flexible
- Accelerator Free
- Latex Free
- Ambidextrous

Packing:

Pouch: 1 pair per pouch

Dispenser: 50 pairs per dispenser box

Outer Case: 4 dispensers per case

Pallet: 50 cases per pallet

Performance Specification:

Freedom from holes - BS EN 455-1	
Water Tight Test	General Inspection Level 1, AQL 1.5

Dimensions – BS EN 455-2	Small	Medium	Large
Palm Width (mm)	80 ± 10	95 ± 10	110 ± 10
Length (mm)	240 min	240 min	240 min

Force at Break – BS EN 455-2	
Throughout shelf life	Minimum 6 Newton
After challenge test	Minimum 6 Newton

Biological Properties – BS EN 455-3	
Powder Level	Less than 2 mg per glove
Protein Content (Latex only)	≤50µg/g using the modified Lowry method

Viral Penetration – ASTM F1671-7	
Phi-X174 Bacteriophage penetration	No visual penetration

Shelf Life Properties – BS EN 455-4	
Currently shelf life is determined through accelerated ageing and is set at 3 years (whilst real time studies are in progress)	

Chemical Compatibility	
Information regarding permeation of cytotoxic/chemotherapy drugs is available on request	

Sterilisation Method – BS EN ISO 11137	
Sterilisation	Gamma Irradiation

Protective gloves against chemicals and micro organisms - BS EN 374	
Resistance to penetration	Waterproof gloves and low chemical protection
Resistance to penetration	Micro organism resistant as defined in EN374-1

Quality Standards:

Manufacturing QMS	EN ISO 9001 / EN ISO 13485
Glove	The BS EN 455 series of standards (parts 1,2,3 and 4)
Sampling & Inspection	ISO2859-1
MDD Requirement	Medical Devices Directive 93/42/EEC (and subsequent amendments)
PPE Requirement	Personal protective equipment directive 89/686/EEC
CE Classification	Class I Sterile Medical Device
CE Classification	Complex Design, category III
Glove Care	Keep away from direct sunlight or fluorescent light. Store at temperature no less than 5°C, no more than 25°C
Sterility Care	Sterile as long as the peel pouch is sealed and undamaged

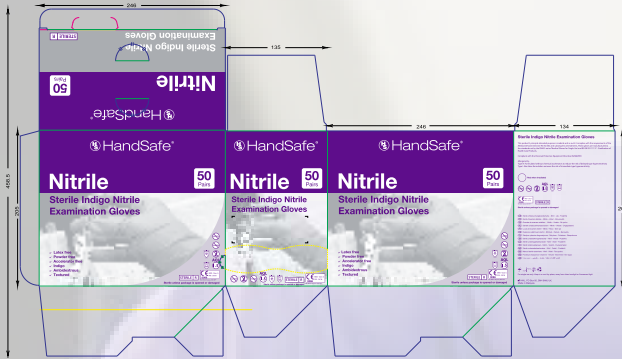


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Packaging Artwork:

Inner



Outer



Pouch:



Dimensions:

Dispenser: L145mm x W135mm x H235mm

Outer: L280mm x W254mm x H418mm

Pouch: W116mm x H116mm

Barcodes:

Size	Small	Medium	Large
Inner	5027550042729	5027550042897	5027550042965
Outer	5027550043023	5027550043191	5027550043269

Packaging Symbols:



Lot number



Latex Free



Keep dry



Date of manufacture



Powder Free



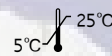
Keep away from sunlight



Use by



Acceptable quality level



Temperature limitation



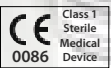
Manufacturer



Sterilization by Gamma irradiation



Recyclable packaging



Compliant with the Medical Devices Directive

EN374-2:2003



Protection against micro-organism and biological hazards



Compliant with the Personal Protective Equipment Directive

EN374-3:2003



Protection against chemical hazards



Single use - do not re-use

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