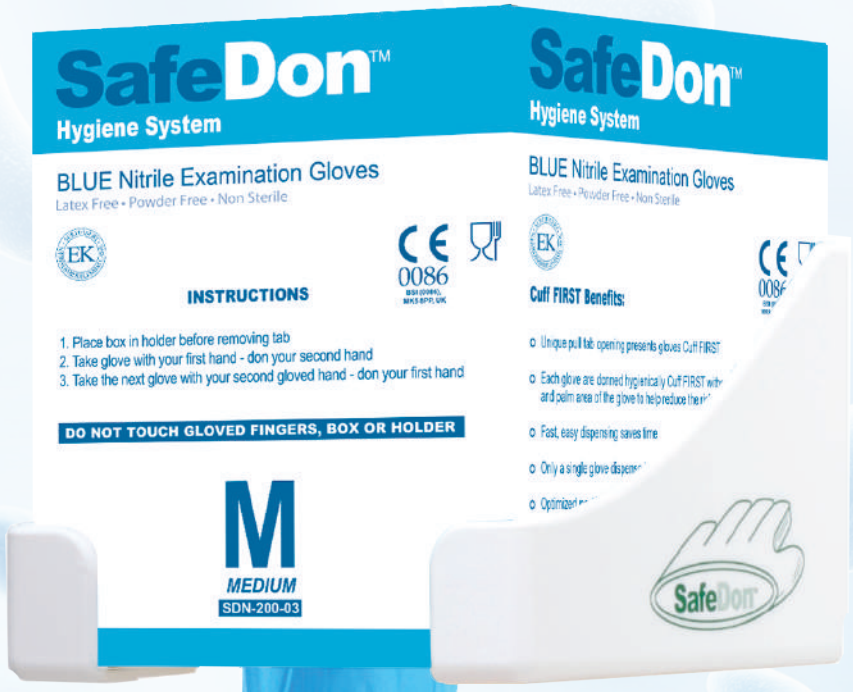
SafeDon™
Hygiene System

Powder Free Synthetic Examination Gloves

SAFEDON HYGIENE SYSTEM NITRILE BLUE
SAFEDON HYGIENE SYSTEM NITRILE WHITE
SAFEDON HYGIENE SYSTEM NITRILE LONG CUFF
SAFEDON HYGIENE SYSTEM VINYL

BLUE Nitrile Examination Gloves
Latex Free • Powder Free • Non Sterile

Patent pending
EP2326557A



The NEW
SafeDon™
Hygiene System

Key Benefits:

- Hygienic system for dispensing and donning gloves.
- Individual gloves dispensed Cuff 1st™, to help reduce the risk of cross contamination.
- Fast, easy dispensing saves time.
- Keeps gloves away from contaminated surfaces.
- Latex Free and Powder Free.

Better Hygiene. Better Safety. Better Economy.

SafeDon™ Hygiene System

BLUE Nitrile Examination Gloves

Latex Free • Powder Free • Non Sterile

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A Vital Part of Your Infectioin Control System

Medical gloves provide protection from unwanted substances for both healthcare professionals and patients. SafeDon Hygiene System Nitrile Gloves meet and exceed international products standards to provide uncompromising protection to its users.

SafeDon Hygiene System

Cross-contamination is a growing concern in any working environment where glove use and adherence to hand hygiene policies are required. Despite the introduction of hand washing initiatives the level of compliance cannot be guaranteed to reach 100 %. International studies continue to show that gloves and traditional glove boxes themselves can be a vehicle for contamination. The new innovative SafeDon Hygiene System dispense only one glove at the time cuff 1st, eliminating touching of the glove most critical surfaces - thumb, finger and palm area - and reduce the risk of cross infections (1-6)

SafeDon Hygiene System is a hygienic initiative which further helps to reduce the risk of cross-contamination.

1. WHO, 2009: WHO Guidelines on Hand Hygiene in Healthcare: a summary 2. Folkehelseinstituttet, 2004: Nasjonal Veileder for handhygiene3. Hughes KA, Cornwall J, Theis J-C, Brooks HJL. Bacterial contamination of unused, disposable non-sterile gloves on a hospital orthopaedic ward, 2013 4. Diaz et al, 2008: Contamination of examination gloves in patient rooms and implications for transmission of antimicrobial-resistant microorganisms 5. Swann-Morton Study, 2009: Six weeks trial with SafeDon 6. Swann-Morton Study, 2010: Six weeks trial with SafeDon

- *SafeDon Hygiene System dispense one glove at the time and eliminates touching of the opening and other "unused" gloves inside*
- *SafeDon Hygiene System eliminates unwanted gloves from falling out of the box and therefore reduces waste*

- *Resists permeation by a wider range of chemicals than natural rubber latex of the same thickness*
- *100% nitrile material eliminates Type I allergic reactions associated with NR-Latex protein*
- *Superior strength and puncture resistance*
- *SafeDon Hygiene System eliminates users from touching the most critical surfaces of the glove: - thumb, fingers and palm area*

CE 0086 BSI (0086), MKS BPP, UK

EK CERTIFIED

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BS EN 388:2003 Mechanical Hazards

BS EN 374:2003 Micro-organism Hazards

GKL BS EN 374-3:2003 Chemical Hazards

PRODUCT INFORMATION

Type: Powder free and non-sterile
Primary Material: Acrylonitrile - butadiene
Powder: No powder lubricant added
Color: Blue (PMS 285 U)
Design and Feature: Ambidextrous, textured surface at fingers and beaded cuff
Packing: 250 gloves per dispenser (240 XL)

Dimensions:

Glove Size	Reorder#	Palm Width (mm)	Length (mm)
Extra-small	SDN-200-01	≤ 80	240 min
Small	SDN-200-02	80 ± 10	240 min
Medium	SDN-200-03	95 ± 10	240 min
Large	SDN-200-04	110 ± 10	240 min
Extra-Large	SDN-200-05	≥ 110	240 min

Thickness:

Location of Thickness Measurements	Singel Wall (mm)
Finger (at 15 mm from the extreme tip)	min. 0.07
Palm (at center of palm)	min. 0.06
Cuff (at 25 mm from cuff end)	min. 0.05

Physical Properties:

Parameters		Before Aging	After Aging
Tensile Strength	(MPa)	≥ 21	≥ 18
Force At Break	(N)	≥ 9	≥ 6

Pre-shipment Quality Inspection:

Criteria	Insp.Level	AQL
Dimension	N=13	Median
Physical Properties	N=13	Median
1000ml Water Leak Test	G-1	1.0
Visual Inspections for Major defects	G-1	2.5
Visual Inspections for Minor defects	G-1	4.0
Powder Free Residue	N=5	N/A

Product Conformance:

- Medial Device: in compliance with European Medical Directive 93/42/EEC (CE Class I)
- EN 455 Parts 1, 2, 3 and 4
- Personal Protective Equipment of Complex Design Category III, in compliance with 89/686/EEC, type tested to EN 420:2003+A1:2009, EN 374-2:2003, EN 374-3:2003 & EN 388:2003, CE 0086
- ASTM D3578
- EK certificate nr: 2387

Quality Assurance:

- US FDA Quality System Regulation (QSR)
- ISO9001Quality System
- ISO13485 Quality Management System

SafeDon™ Hygiene System

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