Technical Data Sheet



AEROuse - Easy Gloves Nitrile Premium Guard

Description:

High quality single use examination and protective gloves made of blue nitrile, powder- and latex-free, with extended and beaded cuffs.

REF: HHS01-PG-PF3-B-...

General Product Information

- · Powder-free examination and protective glove made of latex-free nitrile rubber
- For single use
- Medical Device Class I
- Cat. III Personal protective equipment (PPE)
- **Ambidextrous**
- Textured fingers for a good grip
- Suitable for food contact ISEGA 🟋
- Non-sterile
- Free of latex allergy risk type I (proteins)

Intended Use

The gloves are intended to be used to contribute to prevent cross contaminations in the framework of medical examinations and diagnostic / therapeutic procedures conducted under non-sterile conditions and protect users from substances and mixtures which are hazardous to health and harmful biological agents that may cause very serious consequences or irreversible damage to health.



Packaging Sizes

Size			Dispenser box		Shipping carton		
		Colour code	Content	Dimensions (L x W x H)	Content	Dimensions (L x W x H)	
S	6 - 7			100 pcs 260 x 110 x 68 mm	10 Dispenser boxes		
M	7 - 8		100 pcs			250 v 222 v 272 mm	
L	8 - 9	•				358 x 233 x 272 mm	
XL	9 - 10		90 pcs				

European Importer:

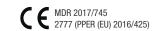
HUM Gesellschaft für Homecare und Medizintechnik mbH Zum Pier 79 | 44536 Lünen | Germany



Hartalega Sdn Bhd C-G-9, Jalan Dataran SD1, Dataran SD PJU9, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia



MDSS GmbH Schiffgraben 41 30175 Hannover, Germany



ID 4083904 Rev. 3.0 | 01.02.2023

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Product Properties

Material				
Base material Nitrile Butadiene Rubber (NBR)				
Accelerators	Contains Zinc Dibutyldithiocarbamate (ZDBC), free of Thiurames and free of Mercaptobenzothiazole (MBT)			

Glove design			
Colour	Blue		
Form	Ambidextrous		
Cuff	Beaded and extended cuff		
Fingers	Textured		
Inner coating	Chlorinated		

Dimensions in mm (EN 455)								
Size Width (Median) Length (Media								
S		86 ± 4						
M		98 ± 4	200 . 10					
L		107 ± 4	290 ± 10					
XL		115 ± 4						

Wall thickness in mm (Median, single wall)				
Finger	0.14 ± 0.02			
Palm	0.09 ± 0.02			

Force at break (Median)		
\geq 6 N (before and after aging)		

Storage and transport conditions
Store in a dry, ventilated area and avoid direct sunlight, fluorescent lighting, heat and moisture. Protect from ozone. Store at temperatures between 5 - 40 °C.
Shelf life: 5 years from manufacturing date

Regulatory Information

Applied Standards:

	EN 455 - Medical gloves for single use
EN 455-1	Part 1: Requirements and testing for freedom from holes (AQL \leq 1.5)
EN 455-2	Part 2: Requirements and testing for physical properties
EN 455-3	Part 3: Requirements and testing for biological evaluation
EN 455-4	Part 4: Requirements and testing for shelf life determination
	EN 374 - Protective gloves against dangerous chemicals and micro-organisms
EN ISO 374-1	Part 1: Terminology and performance requirements for chemical risks
EN 374-2	Part 2: Determination of resistance to penetration
EN 374-4	Part 4: Determination of resistance to degradation by chemicals
EN ISO 374-5	Part 5: Terminology and performance requirements for micro-organisms risks
EN 420	Protective gloves - General requirements and test methods
EN 421	Protective gloves against ionizing radiation and radioactive contamination (Protection against particulate radioactive contamination only, excluding clause 4.3.)
EN 16523-1	Determination of material resistance to permeation by chemicals - Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact
ISO 16604	Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood-borne pathogens - Test method using Phi-X 174 bacteriophage

Complete list of applied standards available upon request.

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Medical Device Information:

Medical Device Class I acc. Regulation (EU) 2017/745 (MDR), EN 455









AQL 1.5

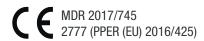
Food Law:

Suitable for food contact acc. 1935/2004/EEC



PPE Information:

Personal Protective Equipment (PPE) Category III acc. Regulation (EU) 2016/425 (PPER), EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 421:2010 (excluding clause 4.3)





EN ISO 374-1:2016/Type B



Tested acc. EN ISO 374-1:2016, EN 16523-1:2015, EN 374-4:2013							
Code Letter Chemical CAS-RN Performance Level Degrade							
J	n-heptane	142-82-5	3	33.9 %			
K	40 % Sodium hydroxide	1310-73-2	6	- 19.9 %			
Р	30 % Hydrogen peroxide	7722-84-1	2	34.5 %			
T	37 % Formaldehyde	50-00-0	6	- 11.0 %			

Permeation performance level	1	2	3	4	5	6
Measured breakthrough time (min)	> 10	> 30	> 60	> 120	> 240	> 480

^{*}Degradation level indicate the change in puncture resistance of the gloves after exposure to the challenged chemicals.

EN ISO 374-5:2016



Tested acc. EN ISO 374-5, ISO 16604				
Protection against viruses	Pass			
Protection against bacteria and fungi	Pass			



This glove does not protect against mechanical risks. Protection against particulate radioactive contamination only, excluding clause 4.3.

Provided information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties.

Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections. For single use only. The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

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