# PROSENSO™ BIODEGRADABLE NITRILE GLOVES

PERFECT FOR USE IN MEDICAL AND FOOD SECTOR







# PROSENSO™ BIODEGRADABLE

### PRODUCT DESCRIPTION

**PROSENSO™** BIODEGRADABLE GLOVES. Specially designed to biodegrade in landfill through microbial process. Our cutting edge biodegradable nitrile gloves are also accellerator free and conforms to all the specifications and certifications you would require for a high quality nitrile glove.

Article number: EWBI035M-XS, EWBI035M-S, EWBI035M-M, EWBI035M-L, EWBI035M-XL

#### **BIOCOMPATIBILITY TESTED**

#### **BIODEGRADABILITY TESTED**

Reference:ISO 10993-10Reference:ASTM D5511Primary Skin Irritation:PassedBiodegradable % at (513 days)43.0 (Test result)Skin Sensitization:PassedResult:Passed

CHARACTE	RISTICS		7	Thickness - single wa	u
All sizes:	<b>Length*</b> min. 240mm		<b>Cuff</b> 0,06±0,02mm	<b>Palm</b> 0,07±0,02mm	<b>Finger</b> 0,09±0,02mm
Palm width:	<b>XS</b>	<b>S</b>	<b>M</b>	<b>L</b>	<b>XL</b>
	76±3mm	84±3mm	94±3mm	105±3mm	113±3mm
Middle finger:	<b>XS</b>	<b>S</b>	<b>M</b>	<b>L</b>	XL
	72±3mm	75±3mm	84±3mm	86±3mm	88±3mm

<sup>\*</sup>in accordance to EN 455-2

### **DESIGN**

Material:	Nitrile	Color:	Pastel green
Powder:	Powder-free	External surface:	Finger-textured
Shape:	Ambidextrous	Protein content:	n/d
Cuff:	Beaded cuff	Sterilization:	Non-sterile

#### PHYSICAL PROPERTIES

	Before Aging:		After Aging:
Force at break:	Minimum 6N	Force at break:	Minimum 6N
Elongation:	Minimum 500%	Elongation:	Minimum 400%
AQL:	1.5		

## PROSENSO™ BIODEGRADABLE

### **HEAVY METAL TESTED**

### **CHEMICAL RESIDUE TESTED**

Reference:	EPA Method 3052	вна:	Not Detected
Cadmium (Cd):	Not Detected	BHT:	Not Detected
Lead (Pb):	Not Detected	DPTU	Not Detected
Mercury (Hg):	Not Detected	ZMBT:	Not Detected
Arsenic (As):	Not Detected	TMTD:	Not Detected
Antimony (Sb):	Not Detected	ZDBC:	Not Detected
Tin (Sm):	Not Detected	ZDEC:	Not Detected
		ZDMC:	Not Detected
		ZMBI:	Not Detected
		ZPMC:	Not Detected

#### **ACCELERATOR FREE TESTED**

## **VIRAL PENETRATION TESTED**

Reference:	ASTM D7558-09	Reference:	ASTM F1671
Total Thiol Vulcanization: Result:	Not Detected Passed	Result	Passed
	. 43334		

### **LOGISTIC DATA**

Gloves in dispenser:100 glovesGloves in carton: $10 \times 100$  glovesDispenser dimension: $20 \times 11 \times 6$  cmCarton dimension: $36 \times 23 \times 21$  cm

**Shelf life:** 3 years

Storage: Store in original packaging in a dry and dark place at room temperature. Protect from heat,

humidity, bright light and ozone.

## TECHNICAL DATA SHEET

#### **QUALITY MANAGEMENT**

Product related standards: EN ISO 374-1:2016 / Type B | EN 374-2:2003 | EN 374-4:2013 | EN374-3:2003 |

> EN 374-5:2016 VIRUS | EN 16523-06:2017 | EN 420:2003+A1:2009 | EN 455-1:2000 | EN 455-2:2009 | EN 455-3:2006 | EN 455-4:2009 |

Quality certificates: ISO 9001:2015

ISO 13485:2016

Food safety: Suitable for foodstuffs in accordance to Framework Regulation (EC) No 1935/2004

German Food and Feed Code (LFGB)

Recommendation of the German Federal Institute for Risk Assessment (BfR XXI)

Category 3 "For short contact with foodstuffs"

Medical Device: Medical Device, Class 1, in accordance to MDR 2017/745

PPE: Personal protective equipment in accordance to Regulation (EU) 2016/425

CE Category III: For irreversible or mortal risks

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#### PLEASE NOTICE:

Glove length is appropriate to the use where the risk is minimal to the wrist area.

The product needs to be checked for the correct size and suitability with regard to its intended use. Before use check for damage and do not use damaged or unsuitable gloves. The gloves are intended for single use only and shall be disposed on a regular basis.

The product may cause allergic reactions on sensitive people. Particular caution must be exercised if the user has any known or suspected hypersensitivity.

The information above are to be considered as typicial values in the standard version based on the manufacturer's information. Subject to modification. The gloves shall only be used for its intended purpose.

Technical data sheet issued by:

Production:

Eastwest Medico Aps Gotfred Rodes Vej 2 2920 Charlottenlund Denmark

Produced in Malaysia for PROSENSO™/Eastwest Medico Ltd., Denmark.





PROSENSO<sup>™</sup> IS A BRAND OWNED BY EASTWEST MEDICO LTD., DENMARK

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