

TECHNICAL SHEET

ECOGLOVELY PF GREEN 35

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Commercial Name:



ECOGLOVELY PF GREEN 35

Typology:

Examination and exploration glove in biodegradable acrylic nitrile, disposable, non-sterile, free from lubricating powder, free from accelerators, internally chlorinated to facilitate donning, pastel green colour, right and left interchangeable anatomical shape (ambidextrous) and textured fingers.

The cuffs have an anti-roll elastic band which reinforces the end of the glove, increases the fit and prevents the cuff from rolling up.

The glove is long enough to allow it to adhere to the gown in any position of the hand. Glove made in a single body, free of welds and burrs, has an excellent consistency, excellent elasticity, and softness such as to guarantee perfect adherence and excellent sensitivity to the operator.

The high ergonomics and biocompatibility allow prolonged use without fatigue.

Glove suitable for food contact for different types of food.

Weight $3.5 \text{ g} \pm 0.2 \text{ g}$ (size M),

average thickness 0.07 mm

(finger thickness $0.10 \pm 0.02 \text{ mm}$, palm thickness $0.06 \pm 0.02 \text{ mm}$, cuff thickness $\geq 0.05 \text{ mm}$).

Accelerator Free:

Accelerator content in the glove compound null.

Manufacturer:

WAYS S.p.A.
Via Francesco Crispi, 26
60027 Osimo (AN) – Italia

Product Code:

DAR NI BIO + SIZE

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CE Marking: Medical Device - class I, pursuant to Regulation (EU) 2017/745 on Medical Devices.
Personal Protective Equipment - Category III, pursuant to Regulation (EU) 2016/425 on Personal Protective Equipment.
Certification issued by SATRA Technology Europe Limited. Notified Body n. 2777.

EMDN: T01020204

Shelf life: 3 years

Intended use: Gloves suitable for the following activities (within the limits of the marked protective levels):
hospital and outpatient use for high-risk interventions for the operator in the healthcare, diagnostics, endoscopy and laboratory, cleaning, chemical industry, workshop, electronics, food processing sectors.

Device Dimensions: EN 455-2:2009+A1:2011

SIZE	5 – 5.5 XS	6 – 6.5 S	7 – 7.5 M	8 – 8.5 L	9 – 9.5 XL
Minimum Length [mm]	240	240	240	240	240
Palm Width [mm]	≤ 80	80 ± 10	95 ± 10	110 ± 10	≥ 110

Sizer Range

SIZE	ARTICLE CODE	Basic UDI-DI	RDM
S	DAR NI BIO S	8051884684284	2393830
M	DAR NI BIO M	8051884684307	2393847
L	DAR NI BIO L	8051884684321	2393849
XL	DAR NI BIO XL	8051884684345	2393850

Pinhole checks, AQL – EN 455-1 – sampling procedure according to ISO 2859-1

DEFECT	INSPECTION LEVEL	AQL
Micro-holes	G – I	0.65

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Packaging: 100 gloves/dispenser – 10 dispensers/carton.

The gloves are packaged in cardboard dispensers of 100 pieces, FSC* certified, arranged in such a way as to allow the extraction of only one glove at a time through the special opening without the aid of any means.

The dispensers are placed in rigid cardboard packaging, so that the smaller side of the dispenser is at the top of the carton.

This is in order to maintain the integrity of the dispenser during transport.

The cartons are impact-resistant, taped closed, dust-tight, and suitable for stacking.

**Forest Stewardship Council (or FSC for short) is an international non-profit NGO.*

FSC has created an internationally recognized forest certification system whose purpose is the correct forest management and the traceability of derived products.

The FSC 100% label is affixed to products consisting exclusively of inputs from FSC certified forests.

Certifications and tests:

The glove has been tested according to the following reference standards:

- EN 455-1/2/3/4 (AQL for absence of holes, dimensions, physical properties, biological safety, determination of shelf life)
- EN ISO 374-1, EN ISO 374-2, EN 374-4, EN ISO 374-5 – EN 16523-1 (resistance to penetration and permeation by chemical substances and microorganisms, degradation tests)
- EN 420 (general requirements)
- ASTM D5511 (anaerobic biodegradation)

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CERTIFICATIONS AND TESTS: FUNCTIONS / PROTECTIVE LEVELS			
Applicable requirements of Regulation (EU) 2016/425	Category III Personal Protective Equipment		
 EN 420:2003+A1:2009 General Requirements	The glove meets the general requirements for design and manufacture, harmlessness, comfort, and efficiency. Dexterity 5		
 EN ISO 374-1:2016 Type C Protective gloves against dangerous chemicals and microorganisms	CHEMICAL PRODUCT	PERMEATION LEVEL DETECTED EN 16523-1:2015	LEVEL OF DEGRADATION EN 374-4:2013
	(K) Sodium hydroxide 40% solution	6	-34.9%
	(P) 30% hydrogen peroxide	1	4.9%
	(T) 37% formaldehyde	5	20.3%
 EN ISO 374-5:2016 Protective gloves against dangerous chemicals and microorganisms	CHEMICAL PRODUCT	DETERMINED LEVEL	CHEMICAL RISKS
	Protection against bacteria and fungi	Test passed	
	Protection against viruses	Test passed	

Food Contact



Recommended for use for short and repeated contact at 40°C with acidic, alcoholic, and fatty foods.

SUBSTANCES	YES	NO
Acids		X
Spirits	X	
Oily and greasy	X	

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Labeling:

the following information is indicated on the glove dispenser:

- Commercial Name
- Article Code
- Size in letters
- CE marking as DM and as PPE (indicating the acronym of the Notified Body)
- Informative Note Pictogram 
- EN ISO 374-1 Type C Pictogram 
- EN ISO 374-5 Pictogram 
- Food Contact Pictogram 

The information and symbols used for the Medical Device, in the labeling and in the information, comply with the EN 1041:2008+A1:2013 and EN ISO 15223-1 standards.

Allergenic substances: totally latex-free glove (latex free) in the product, in the primary and secondary packaging and in the production process.

It has a low content of potentially allergenic additives; therefore, it is particularly suitable for personnel sensitive to latex proteins and for use in latex-free departments.

Lubricating system: glove free from lubricating powder.

Internally chlorinated to make the internal surface equally smooth, in order to guarantee excellent fit and fit characteristics and allow easy use even with wet hands and minimize the risk of allergic reactions.

Shelf Life: The shelf life of a powder-free biodegradable nitrile examination glove is 3 years, considering that the storage instructions are respected.

Biodegradability: Glove tested in accordance with ASTM D5511 to determine anaerobic biodegradation of plastics under high solids anaerobic digestion conditions, and degrades 36.7% in 513 days in operational landfills.

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Warnings: Before use, check that each glove is free from defects or imperfections.

If in doubt, discard the glove and replace it with another one.

If the gloves are used in contact with chemicals:

- make sure that the chemical cannot meet the skin via the cuff;
- avoid direct contact of the chemical substance with the skin, even if this substance is declared harmless;
- in case of accidental contact with the skin, wash thoroughly with soap and water;
- remove and discard gloves as quickly as possible after use.

Avoid contact with ketone solvents.

The gloves must not be used in applications requiring protection against mechanical or thermal risk. Wear gloves with clean, dry hands.

Use dry gloves inside.

Instructions for use: consult the information printed on the product dispenser and the manufacturer's information note.

Specific storage conditions: store in a dry place away from light and heat at a temperature between 5°C and 35°C.

Keep away from ozone sources or flammable sources.

The hygienic conditions of the product are guaranteed only when the package is intact.

Keep the packaging for further information and to ensure traceability.

Quality controls in production and on the finished product: the manufacturer has established and currently carries out a series of procedures to ensure that the product is identified, controlled, and tested for compliance with a series of specific requirements.

Disposal: Used gloves may be contaminated with infectious agents or other hazardous materials.

Disposal must be carried out in compliance with the national regulations in force.

Incineration or landfilling must be carried out under controlled conditions in accordance with applicable national regulations.

Manufacturer Certifications:

ISO 9001:2015	ISO 13485:2016	ISO 14001:2015
Certificate n. 1517.2022 issued by IMQ S.p.A.	Certificato n. 1514.2022 issued by IMQ S.p.A.	Certificato n. 0875.2018 issued by IMQ S.p.A.

RAYS S.p.A.
Products specialist
Safety Division