

Section 3- User Manual / PPE to fit an individual user

User Manual

Item

Disposable Vinyl Gloves Powdered & Powder Free

Produced in conformance with the regulation (EU) No 2016/425 of the European Parliament and of the council and national standards EN ISO 374-1:2016+A1:2018, EN 374-2: 2014, EN 16523-1:2015, EN 420:2003+A1: 2009, EN 374-4:2013, EN ISO 374-5:2016. The relevant information and standards of the product are listed in the user manual in correspondence with Declaration of Conformity that can be found at <https://www.regaldisposables.co.uk/comformity>

Features

- Ambidextrous
- Straight Fingers
- Beaded Cuff
- Smooth Surface

















Instruction for individual user

1. This product is a single-use item, do not reuse.
2. The product packages in Paper Dispenser Boxes, a paper carton then encloses these Dispenser packages to be transferred. It should be stored to avoid excessive temperatures of above 40 degrees Celsius (104 degrees Fahrenheit) and should avoid exposure to direct sunlight, fluorescent lighting, and X-Ray radiation.
3. Users of this product should consider its adaptation to the environment, for example: the user is able to remove the powder from powdered gloves by wet wipes, sponges, or any other effective way.
4. This product provides a biological and chemical barrier of protection. For information, please refer to label.
5. If this product is used and contaminated, it should be disregarded/disposed of using an appropriate method.
6. If user experiences a reaction such as itchy skin, rash, or any other allergic reaction to this product, then the user should discontinue use immediately and seek medical advice.
7. If the wearer is using sharp objects, devices and/or materials they will cause ruptures or holes in the material, please be cautious.

Warning

This product can cause skin irritation or reactions for some wearers. It should be used with caution. If any symptoms arise, discontinue use immediately and seek medical advice.

Label

item	Symbol	Symbol Explanation	item	Symbol	Symbol Explanation
1		Date of manufacture	9		Product is latex-free
2		Manufacturer	10		Instructions for use attached to the product
3		Batch code (Manufacturer's Code)	11		Food safe
4		Use-by-date. Indicates the date after which the medical device is not to be used.	12		In conformance with EN ISO374-1:2016/type C
5		Do not re-use Product for single use only	13		In conformance with EN ISO 374-5:2016
6		CE mark (with NB)	14		NON-STERILE
7		Keep dry	15		Keep out of Direct Sunlight
8		Temperature limits to which the medical device can be safely exposed	16		Made using recycled packaging

Relevant tests through:

EN 374-4:2013	Mean Degradation
40% Sodium hydroxide / K	-9.3%

EN 16523-1:2015	Performance Level	Breakthrough times
40% Sodium hydroxide / K	6	>480 min

EN 420:2003+A1: 2009	Pass
EN ISO 374-2: 2014	Pass
EN ISO 374-5:2016	Pass

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Doc. No.	UMV
Rev. No.	1A
Rev. Date	25.08.2021

CE-Type testing through: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9,
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Notified Body number 2797

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