

# **Declaration of Conformity – CE**

Supermax Healthcare Ltd hereby confirms that the product mentioned below complies with EU & UK Regulations (EU) 2016/425 on Personal Protective Equipment (PPE) and applicable standards and is manufactured according to ISO9001:2015 standard requirements. The Declaration of Conformity is issued under the sole responsibility of Supermax Healthcare Ltd.

S/7	M/8	L/9	XL/10
301-7	301-8	301-9	301-10

#### Classification of the product:

• CAT II PPE (EU) 2016/425 Regulation on PPE, as amended and as applicable also into UK Law.

### Product mentioned above complies with:

 The provisions of Personal Protective Equipment (PPE) Regulation (EU) 2016/425, including the General Safety Requirements (Annex II), Module B EU-Type Examination Certification, Conformity to type for Category III PPE.

#### **Certification:**

- EU Type Examination Certificate issued by Notified Body: CTC Groupe, 4 rue Hermann Frenkel, 69367 Lyon cedex 07, France
- Notified Body Number 0075
- Certificate No. 0075/3074/162/01/23/0119

#### **User Information:**

• Store in dry, clean condition and away from direct sunlight. Keep in the original packaging. See Instructions for Use for details on warnings and precautions in using this product.

#### **Gloves tested according to Harmonised Standards:**

#### Product is in conformity with Regulation EU 2016/425 on PPE, Category II Dexterity level 5

Testing requirement	Description	Test Result	Ex	Explanation of test and level			
EN ISO 21420:2020	General Requirements	Pass	Risk Category, Sizing, Labelling				
EN388:2016 +A1:2018 3101X	Mechanical Hazards	3	Ab	Abrasion Resistance: Level 0-4			
		1	Co	Coupe Test, Blade Cut Resistance: Level 0-5			
		0	Tea	Tear Resistance: Level 0-4			
		1	Pu	Puncture Resistance: Level 0-4			
		X	TD	TDM Cut Resistance, ISO 13997: Level A-F			
			'X'	'X' Not Tested			
EN ISO 374-1: 2016/Type B	Tested Chemical		Letter	Permeation performance levels	Degradation Value		
	n-Heptane		J	4	29.7%		
	Sodium hydroxide 40%		K	6	6.8%		
	Sulphuric acid 96%		L	2	68.7%		

## Responsibility

• This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer as indicated below:

#### **Manufacturer**

Manufactured in China on behalf of Supermax Healthcare Limited, 12-16 Titan Drive, Fengate, PE1
5XN, Peterborough, United Kingdom

Authorised by:

Daniel Todd Group QA/RA & Technical Manager

Supermax Healthcare Ltd

Date: 23/09/2024

\*This declaration is valid for period of 2 years from the date of issue or until any changes to regulations or products are applicable.