

AURELIA® 203

15gg Grey Nylon Spandex Glove with a Black Micro Foam Nitrile Coating

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	XXL/11
203-7	203-8	203-9	203-10	203-11

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 II PPE.
- The provisions of Regulation (EC) No 1935/2004 of the European Parliament and of the council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Secotion 30 and 31 with amendments and BfR recommendation.

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. 0075/3048/162/06/22/1242
- Testing in accordance with the provisions of Regulation (EC) No 1935/2004 of the European Parliament and of the council of 27 October 2004, German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Secotion 30 and 31 with amendments and BfR recommendation.

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	Explanation of test and level
EN ISO 21420:2020	General Requirements	Pass	Risk Category, Sizing, Labelling
	Mechanical Hazards	4	Abrasion Resistance: Level 0-4
		1	Coupe Test, Blade Cut Resistance: Level 0-5
		3	Tear Resistance: Level 0-4
		1	Puncture Resistance: Level 0-4
		A	TDM Cut Resistance, ISO 13997: Level A-F
			'X' Not Tested

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: 02/12/2024

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