
	<b>EU Declaration of Conformity</b>	TF-75
	Nitrile Powder Free Gloves	
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## Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices

This EU declaration of conformity is issued under the sole responsibility of the manufacturer to state that the requirements specified in Regulation (EU) 2017/745, and other applicable Union legislation as listed in Annex 1 to this declaration, have been fulfilled in relation to the devices listed in Annex 4 to this declaration.

<b>Name and address of Manufacturer:</b>	Crest Medical Limited. Unit 5 Farrell Industrial Estate, Howley Lane, Warrington WA1 2PB, UK				
<b>Single Registration Number (SRN):</b>	GB-MF-000025649				
<b>Basic UDI-DI:</b>	5039139TF75C1NSM2				
<b>Product Name:</b>	Nitrile Powder Free Gloves				
<b>Product Codes or Catalogue Numbers:</b>	As per Annex 4 – Device Listing				
<b>Intended Purpose:</b>	Durable, comfortable gloves for first aid and general household use.				
<b>GMDN Code:</b>	56286	<b>EMDN Code:</b>	T0199		
<b>Risk Class:</b>	Class I	<b>Classification Rules:</b>	Rule 1		
<b>Sterile:</b>	No	<b>Measuring Function:</b>	No	<b>Reusable Surgical Inst.:</b>	No
<b>Common Specifications (CS):</b>	As per Annex 2 – Common specifications See also: Annex 3 Applicable Standards				
<b>Notified Body:</b>	N/A				
<b>Conformity Assessment Procedure:</b>	Article 52(7)				
<b>Certificate Type(s) and Reference Number(s):</b>	ISO 13485 Certificate: GB98/12980				
<b>EU Authorised Representative:</b>	CMC Medical Devices& Drugs S.L C/Horacio Lengo N 18, CP29006, Málaga-Spain				
<b>Additional Information:</b>	None				

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**Declaration Signature:**


Date: 16 December 2025

Location: As above

Name: Matthew Courtney

Position: Director and person responsible for regulatory compliance of the manufacturer.

Signed:  \_\_\_\_\_

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### ANNEX 1 – Union legislation

The devices listed in Annex 4 are in conformity with the following Union legislation:

- Regulation (EU) 2017/745

### ANNEX 2 – Common Specifications (CS)

There are currently no CS's which apply to these devices.

### ANNEX 3 – Applicable Standards

Standard Ref.	Standard title
ISO 13485	Medical Devices – Quality Management Systems –Requirements for regulatory purposes.
EN ISO 14971	Medical devices. Application of risk management to medical devices
EN ISO 15233-1	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
EN 62366-1	Medical Devices – Application of usability in engineering to medical devices.
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system process.
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity
EN ISO 10993-10	Biological Evaluation of Medical Device: Test for skin sensitisation
EN ISO 10993-23	Biological Evaluation of Medical Device: Test for skin irritation

### ANNEX 4 – Device Listing

Product Code / Catalogue No.	Device Description/Name
71530	Blue Dot Small Nitrile Powder- Free Gloves (1 Pair)
71531	Blue Dot Medium Nitrile Powder- Free Gloves (1 Pair)
71531a	Blue Dot Medium Nitrile Powder- Gloves (3 Pairs)
71532	Blue Dot Large Nitrile Powder-Free Gloves (1 Pair)
71532a	Blue Dot Large Nitrile Powder-Free Gloves (3 Pairs)
71533	Blue Dot Extra Large Nitrile Powder-Free Gloves (1Pair)
40943	Medikit Large Disposable Nitrile Powder Free Gloves (1 Pair)
71532SVR	Blue Dot (Samaritans) Nitrile Powder Free Gloves
F18015-M	St John Ambulance Nitrile Powder Free Gloves Medium (1 Pair)
F18015-L	St John Ambulance Nitrile Powder Free Gloves Large (1 Pair)
R04224	Wallace Cameron Nitrile Powder Free Gloves Large (3 Pairs)
R04224S	Wallace Cameron Sustainable Nitrile Gloves (Each)