

UKCA Declaration of Conformity

Category III Personal Protective Equipment



Product Description: Blue Medical Grade Nitrile Disposable Gloves

Product Code: 14HC500, 14HC600, 14HC700, 14HC800

Risk Category: This product has been identified as being risk category III PPE as defined in Annex I of Regulation 2016/425 on personal protective equipment, as amended to apply in GB.

Manufacturer: Arco Limited, P.O. Box 21, 1 Blackfriargate, Hull, HU1 1BH, United Kingdom.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment

The product identified above is in conformity with the applicable essential health & safety requirements of Annex II of Regulation 2016/425 on personal protective equipment, as amended to apply in GB, standard(s) detailed below.

Applied Standard(s): EN420:2003+A1:2009; EN ISO 374-1:2016/A1:2018; EN ISO 374-5:2016
EN ISO 21420:2020

The PPE is identical to that which is the subject of a Type-Examination (Module B)

Performed by: Eurofins Textile Testing Spain, S.L.U

Approved Body No. 2865

and issued the Type - Examination certificate:

Certificate No. UE-00516/00

Date of issue: 24-Jan-2024

Expiry Date: 24-Jan-2029

Conformity to type:

As required for risk category III PPE the product(s) described above is/are subject to conformity assessment based on either, internal production control plus supervised product checks at random intervals (Module C2) or on quality assurance of the production process (Module D) under the surveillance of the notified body;

Additional information: Eurofins Textile Testing Spain, S.L.U NB 2865
The EU B Type Certificate is used as the basis to demonstrate conformity for GB

Signed for on behalf of Arco Ltd,

Name: Philip Atkinson

Position in company: Technical Compliance Manager

Signature:

Phil Atkinson

Date: 24-Jan-2024

EU Declaration of Conformity

Category III Personal Protective Equipment



Product Description: Blue Medical Grade Nitrile Disposable Gloves

Product Code: 14HC500, 14HC600, 14HC700, 14HC800

Risk Category: This product has been identified as being risk category III PPE as defined in Annex I of Regulation (EU) 2016/425

Manufacturer: Arco Limited, P.O. Box 21, 1 Blackfriargate, Hull, HU1 1BH, United Kingdom.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment

The product identified above is in conformity with the applicable essential health & safety requirements of Annex II of the PPE Regulation (EU) 2016/425 and standard(s) detailed below.

Applied Standard(s): EN420:2003+A1:2009; EN ISO 374-1:2016/A1:2018; EN ISO 374-5:2016
EN ISO 21420:2020

The PPE is identical to that which is the subject of an EU Type-Examination (Module B)

Performed by: Eurofins Textile Testing Spain, S.L.U

Notified Body No. 2865

and issued the EU Type- Examination certificate:

Certificate No. UE-00516/00

Date of issue: 24-Jan-2024

Expiry Date: 24-Jan-2029

Conformity to type:

As required for risk category III PPE the product(s) described above is/are subject to conformity assessment based on either, internal production control plus supervised product checks at random intervals (Module C2) or on quality assurance of the production process (Module D) under the surveillance of the notified body;

Additional information: Eurofins Textile Testing Spain, S.L.U
NB 2865

Signed for on behalf of Arco Ltd,

Name: Philip Atkinson

Position in company: Technical Compliance Manager

Signature:

Phil Atkinson

Date: 24-Jan-2024

UKCA Declaration of Conformity

Medical Devices

arco[®]
Experts in Safety



Medical Device Name(s): **Arco HC106 Exam Gloves - Blue medical grade nitrile disposable gloves**
EUDAMED Basic UDI-DI: **5024273HC106FB**
GMDN Code: **56286**

Virtual Manufacturer

Name: **Arco Ltd.**
Address: **PO Box 21, 1 Blackfriargate, Hull HU1 1BH, UK**
Email: **Diana.Russell@arco.co.uk**
Country of Manufacture: **China**
Representative: **Diana Russell (QA/RA Manager)**
UK-REP: **Not Applicable (Arco is based within the UK)**

Standards Applied

UK MDR 2002 (current edition)

ISO 9001:2015

**EN ISO 14971:2019
IEC 62366-1:2015**

Registration Body

Name: **Not Applicable - Self-declaration devices**
Address: **Not Applicable**

Means of Conformity

ARCO Ltd. declares that the device(s) listed above and detailed in Annex 1 have been classified as:

Rule 1, Class I, UK MDR 2002 (current edition), Self-declaration medical devices.

ARCO Ltd. declares that the medical device(s) listed above and detailed in Annex 1 meet the provisions of Regulation UK MDR 2002 (current edition). All supporting documentation is retained under the premises of the manufacturer.

Company Approval

Signed: *Diana Russell.*
(Diana Russell – QA/RA Manager)

14/Feb/2024
(Date)

UKCA Declaration of Conformity

Medical Devices



ANNEX 1 Product Details This appendix specifies the products included in the above referenced Declaration of Conformity.

| Product Type | Product Code | Product Name | Product Description | Basic UDI (GMN) |
|---------------------------|--------------|----------------------------------|----------------------------------------------|-----------------|
| Blue - 3.2g - 200 per box | 14HC600 | ARCO® HC106 Exam Gloves (Parent) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106F8 |
| Blue - 3.2g - 200 per box | 14HC606 | ARCO® HC106 Exam Gloves XS (6) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106F8 |
| Blue - 3.2g - 200 per box | 14HC607 | ARCO® HC106 Exam Gloves S (7) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106F8 |
| Blue - 3.2g - 200 per box | 14HC608 | ARCO® HC106 Exam Gloves M (8) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106F8 |
| Blue - 3.2g - 200 per box | 14HC609 | ARCO® HC106 Exam Gloves L (9) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106F8 |
| Blue - 3.2g - 200 per box | 14HC610 | ARCO® HC106 Exam Gloves XL (10) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106F8 |
| Blue - 3.2g - 200 per box | 14HC611 | ARCO® HC106 Exam Gloves XXL (11) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106F8 |

| Product Type | Product Code | Product Name | Product Description | Basic UDI (GMN) |
|---------------------------|--------------|----------------------------------|----------------------------------------------|-----------------|
| Blue - 3.2g - 100 per box | 14HC500 | ARCO® HC105 Exam Gloves (Parent) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC506 | ARCO® HC105 Exam Gloves XS (6) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC507 | ARCO® HC105 Exam Gloves S (7) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC508 | ARCO® HC105 Exam Gloves M (8) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC509 | ARCO® HC105 Exam Gloves L (9) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC510 | ARCO® HC105 Exam Gloves XL (10) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC511 | ARCO® HC105 Exam Gloves XXL (11) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |

UKCA Declaration of Conformity

Medical Devices



| Product Type | Product Code | Product Name | Product Description | Basic UDI (GMN) |
|--------------------------|--------------|----------------------------------------------|--------------------------------------------------------|-----------------|
| Blue - 6.5g - 50 per box | 14HC700 | ARCO [®] HCl07 Exam Gloves (Parent) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC706 | ARCO [®] HCl07 Exam Gloves XS (6) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC707 | ARCO [®] HCl07 Exam Gloves S (7) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC708 | ARCO [®] HCl07 Exam Gloves M (8) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC709 | ARCO [®] HCl07 Exam Gloves L (9) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC710 | ARCO [®] HCl07 Exam Gloves XL (10) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC711 | ARCO [®] HCl07 Exam Gloves XXL (11) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |

| Product Type | Product Code | Product Name | Product Description | Basic UDI (GMN) |
|---------------------------|--------------|----------------------------------------------|---------------------------------------------------------------|-----------------|
| Blue - 3.2g - 100 per box | 14HC800 | ARCO [®] HCl08 Exam Gloves (Parent) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC806 | ARCO [®] HCl08 Exam Gloves XS (6) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC807 | ARCO [®] HCl08 Exam Gloves S (7) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC808 | ARCO [®] HCl08 Exam Gloves M (8) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC809 | ARCO [®] HCl08 Exam Gloves L (9) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC810 | ARCO [®] HCl08 Exam Gloves XL (10) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC811 | ARCO [®] HCl08 Exam Gloves XXL (11) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |

UKCA Declaration of Conformity

Medical Devices



Additional Comments

EU Declaration of Conformity

Medical Devices

arco[®]
Experts in Safety



Medical Device Name(s): Arco HC106 Exam Gloves - Blue medical grade nitrile disposable gloves

EUDAMED Basic UDI-DI: 5024273HC106FB

SRN: GB-MF-000033950 EMDN Code: T01020204

Virtual Manufacturer

Name: Arco Ltd.

Address: PO Box 21, 1 Blackfriargate, Hull HU1 1BH, UK

Email: Diana.Russell@arco.co.uk

Country of Manufacture: China

Representative: Diana Russell (QA/RA Manager)

EU-REP: European Healthcare & Device Solutions (Ireland) Ltd.

Address: Stratton House, Bishopstown Road, Cork T12 Y9TC

Country: Ireland (SRN – IE-AR-000003999)

Standards Applied

EU MDR 2017/745 - as amended within [EU] 2023/607

ISO 9001:2015

EN ISO 14971:2019
IEC 62366-1:2015

Registration Body

Name: Not Applicable - Self-declaration devices

Address: Not Applicable

Means of Conformity

ARCO Ltd. declares that the device(s) listed above and detailed in Annex 1 have been classified as:

(Rule 1, Class I, MDR 2017/745 – as amended within [EU] 2023/607, Annex VIII; Self-declaration devices)

ARCO Ltd. declares that the medical device(s) listed above and detailed in Annex 1 meet the provisions of Regulation MDR 2017/745 (as amended within EU 2023/607). All supporting documentation is retained under the premises of the manufacturer.

Company Approval

Signed: Diana Russell
(Diana Russell – QA/RA Manager)

14/ Feb/ 2024
(Date)

EU Declaration of Conformity

Medical Devices



Experts in Safety

ANNEX 1 Product Details

This appendix specifies the products included in the above referenced Declaration of Conformity.

| Product Type | Product Code | Product Name | Product Description | Basic UDI (GMN) |
|---------------------------|--------------|-----------------------------------|----------------------------------------------|-----------------|
| Blue - 3.2g - 200 per box | 14HC600 | ARCO® HCl106 Exam Gloves (Parent) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106FB |
| Blue - 3.2g - 200 per box | 14HC606 | ARCO® HCl106 Exam Gloves XS (6) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106FB |
| Blue - 3.2g - 200 per box | 14HC607 | ARCO® HCl106 Exam Gloves S (7) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106FB |
| Blue - 3.2g - 200 per box | 14HC608 | ARCO® HCl106 Exam Gloves M (8) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106FB |
| Blue - 3.2g - 200 per box | 14HC609 | ARCO® HCl106 Exam Gloves L (9) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106FB |
| Blue - 3.2g - 200 per box | 14HC610 | ARCO® HCl106 Exam Gloves XL (10) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106FB |
| Blue - 3.2g - 200 per box | 14HC611 | ARCO® HCl106 Exam Gloves XXL (11) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC106FB |

| Product Type | Product Code | Product Name | Product Description | Basic UDI (GMN) |
|---------------------------|--------------|-----------------------------------|----------------------------------------------|-----------------|
| Blue - 3.2g - 100 per box | 14HC500 | ARCO® HCl105 Exam Gloves (Parent) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC506 | ARCO® HCl105 Exam Gloves XS (6) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC507 | ARCO® HCl105 Exam Gloves S (7) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC508 | ARCO® HCl105 Exam Gloves M (8) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC509 | ARCO® HCl105 Exam Gloves L (9) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC510 | ARCO® HCl105 Exam Gloves XL (10) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |
| Blue - 3.2g - 100 per box | 14HC511 | ARCO® HCl105 Exam Gloves XXL (11) | Blue Medical Grade Nitrile Disposable Gloves | 5024273HC105F9 |

EU Declaration of Conformity

Medical Devices



| Product Type | Product Code | Product Name | Product Description | Basic UDI (GMN) |
|--------------------------|--------------|----------------------------------------------|--------------------------------------------------------|-----------------|
| Blue - 6.5g - 50 per box | 14HC700 | ARCO [®] HCl07 Exam Gloves (Parent) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC706 | ARCO [®] HCl07 Exam Gloves XS (6) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC707 | ARCO [®] HCl07 Exam Gloves S (7) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC708 | ARCO [®] HCl07 Exam Gloves M (8) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC709 | ARCO [®] HCl07 Exam Gloves L (9) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC710 | ARCO [®] HCl07 Exam Gloves XL (10) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |
| Blue - 6.5g - 50 per box | 14HC711 | ARCO [®] HCl07 Exam Gloves XXL (11) | Blue Long Cuff Medical Grade Nitrile Disposable Gloves | 5024273HC107FD |

| Product Type | Product Code | Product Name | Product Description | Basic UDI (GMN) |
|---------------------------|--------------|----------------------------------------------|---------------------------------------------------------------|-----------------|
| Blue - 3.2g - 100 per box | 14HC800 | ARCO [®] HCl08 Exam Gloves (Parent) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC806 | ARCO [®] HCl08 Exam Gloves XS (6) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC807 | ARCO [®] HCl08 Exam Gloves S (7) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC808 | ARCO [®] HCl08 Exam Gloves M (8) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC809 | ARCO [®] HCl08 Exam Gloves L (9) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC810 | ARCO [®] HCl08 Exam Gloves XL (10) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |
| Blue - 3.2g - 100 per box | 14HC811 | ARCO [®] HCl08 Exam Gloves XXL (11) | Blue Accelerator Free Medical Grade Nitrile Disposable Gloves | 5024273HC108FF |

EU Declaration of Conformity

Medical Devices



Additional Comments