Total Quality. Assured.

TEST REPORT

Number: GZHT90992310

Applicant: CIRCLE SQUARE HOLDINGS LTD
7 BELL YARD, HOLBORN, LONDON,
WC2A 2JR, UNITED KINGDOM

Date: Sep 30, 2020

Attn: ANDREW PRINGLE

Sample Description:

Four hundred (400) pieces of submitted samples said to be Nitrile Medical gloves in Blue.

| | | |
|---|---|---|
| Standard | : | EN 455-1:2000<br>EN 455-2:2015<br>EN 455-3:2015 |
| P.O. No. | : | PO-0015 |
| Colors | : | Blue |
| Size Range | : | S, M, L |
| Style Name | : | Sri Trang-Balance Nitrile Gloves |
| Buyer's Name | : | MedicShield (Trading name of Circle Square Holdings Ltd) |
| Vendor | : | MedicShield (Trading name of Circle Square Holdings Ltd) |
| Supplier | : | Henan Tongzhikang Medical Devices Co Ltd |
| Manufacturer | : | Sri Trang-Balance |
| Country Of Origin | : | Thailand |
| Goods Exported To | : | United Kingdom |
| Date Received/Date Test Started | : | Sep 21, 2020/ Sep 21, 2020 |
| Date Final Information Confirmed/ Date Payment Received: | | --/-- |

Test Result Please Refer To Attached Page(S).

Should you have any query on this report, you may contact at gzfootwear@intertek.com

Authorized By:
For Intertek Testing Services Shenzhen Ltd.
Guangzhou Branch

Guiliang Dong
Senior Lab Manager



MI/fionawgyu

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Tests Conducted (As Requested By The Applicant)

1 Watertightness Test For Detection Of Holes (EN 455-1:2000, 5)

| Results | | | Requirement | | | Pass/Fail |
|---|---|---|---|---|---|---|
| Physical Performance | Failure | AQL | Physical Performance | AQL | n [Ac Re] | - |
| Water Leakage | 2 | < 1.5 | No Leakage | 1.5 | 200 [7,8] | Pass |

Remark: n Means Sample Size, Ac Means Acceptance Number, Re Means Rejection Number.

2 Dimensions Of Examination Gloves (BS EN 455-2:2015 / EN 455-2:2015, 4)

| Sample | Size | Measurement | | Requirement | Pass/Fail |
|---|---|---|---|---|---|
| | | Median Length (mm) | Median Width (mm) | | |
| - | Small | 245 | 85 | * | Pass |
| | Medium | 245 | 97 | * | Pass |
| | Large | 242 | 107 | * | Pass |

Remark: *= Dimensions Of Examination / Procedure Gloves

| Size | Median Length (mm) | Median Width (mm) |
|---|---|---|
| Extra Small | ⩾ 240 | ⩽ 80 |
| Small | | 80 ± 10 |
| Medium | | 95 ± 10 |
| Large | | 110 ± 10 |
| Extra Large | | ⩾ 110 |
| Note: The Width Requirements Are For Gloves Made From Natural Rubber Latex And All Other Elastomeric Material. These Dimensions May Not Appropriate For Gloves Made From Other Materials. | | |



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3 Force At Break (EN 455-2:2015, 5.2 & 5.3 & ISO 188:2007)

| Total Number Tested | Result | Requirement | Pass/Fail |
|---|---|---|---|
| 13 | Before Challenge Testing<br>Median Values Of Force At Break | | |
| | 6.5**N** | Min. 6.0 N | P**ass** |
| 13 | After Challenge Testing (70 ℃, 7 Days)<br>Median Values Of Force At Break | | |
| | 6.3**N** | Min. 6.0 N | P**ass** |

Remark:

Requirements Of Median Values Of Force At Break

| | Force At Break (N) | | |
|---|---|---|---|
| | Surgical Gloves | Examination / Procedure Gloves | |
| | a) | b) | c) |
| Throughout Shelf Life Tested According To 5.2 And Within 12 Months Of Manufacture Tested According To 5.3 | ⩾ 9.0 | ⩾ 6.0 | ⩾ 3.6 |
| a) Requirements For All Surgical Gloves. | | | |
| b) Requirements For All Examination Gloves, Except Gloves Made From Thermoplastic Materials (e.g. Polyvinylchloride, Polyethylene). | | | |
| c) Requirements For Gloves Made From Thermoplastic Materials (e.g. Polyvinylchloride, Polyethylene). | | | |

4 Powder-free Gloves (EN 455-3:2015, 5.2 & EN ISO 21171:2006, Method B/ Method C)

| Result | Requirement | Pass/Fail |
|---|---|---|
| 0.1 mg/Glove | ⩽ 2.0 mg/Glove | Pass |



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5 Chemicals (EN 455-3:2015, 4.2)

| Requirements | Pass | Fail | N/A |
|---|---|---|---|
| Gloves Shall Not Be Dressed With Talcum Powder (Magnesium Silicate). | X | | |
| The Manufacturer Shall Disclose, Upon Request, A List Of Chemical Ingredients Either Added During Manufacturing Or Already Known To Be Present In The Product Such As Accelerators, Antioxidants And Biocides That Are Known To Cause Adverse Health Effects Based On Current Data. | X | | |
| Upon Request The Manufacturer Shall Provide Evidence Of The Steps Taken To Reduce The Risk To The End-User Of Exposure To Chemicals Used In The Manufacturing Process Which, Based On Current Data, Are Known To Cause Adverse Health Effects. | X | | |
| Manufacturers May Only Declare The Absence Of A Substance If The Substance Is Not Used In Any Part Of The Manufacturing Process. No Compounds Shall Be Used In The Manufacture Of The Product That Is Known To Form A Substance That Is Subject Of Such A Declaration. | X | | |

**Compliance:** The Submitted Sample **MEETS** The Requirements Of EN 455-3:2015 Clause 4.2 For Chemicals.



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6 Labelling (EN 455-3:2015, 4.6)

| Requirements | | Pass | Fail | N/A |
|---|---|---|---|---|
| Labelling Specified In EN 1041:2008+A1:2013 And The Relevant Symbols Given In EN ISO 15223-1:2012: | | | | |
| 1) | Description Of Sample | X | | |
| 2) | Name And Address Of Manufacturer | X | | |
| 3) | Date Of Manufacture | X | | |
| 4) | Use By Date | X | | |
| 5) | Batch Code/ Lot Number/ Serial Number | X | | |
| 6) | Relevant Information Of Sterility | | | X |
| 7) | Relevant Information Of Single Use | X | | |
| 8) | Storage conditions | X | | |
| In Addition To The Labelling Specified In EN 1041:2008+A1:2013 And The Relevant Symbols Given In EN ISO 15223-1:2012, The Following Requirements Apply: | | | | |
| a) | Medical Gloves Containing Natural Rubber Latex Shall Be Labelled On The Packaging Of At Least The Smallest Packaging Unit With The EN ISO 15223-1:2012 Symbol For Latex (Reference Number 5.4.5).<br><br>The Labelling Shall Include The Following Or Equivalent Warning Statement Together With The Symbol (Product) Contains Natural Rubber Latex Which May Cause Allergic Reactions, Including Anaphylactic Responses; | | | X |
| b) | The Labelling Shall Include A Prominent Indication Of Whether The Glove Is Powdered Or Powder-Free; | X | | |
| c) | Sterile Powdered Gloves Shall Be Labelled With The Following Or Equivalent: 'CAUTION: Surface Powder Shall Be Removed Aseptically Prior To Undertaking Operative Procedures In Order To Minimize The Risk Of Adverse Tissue Reactions';<br>(NOTE 1 This Caution Statement Can Be Given On The Inner Wrapping.) | | | X |
| d) | For Any Medical Glove Containing Natural Rubber Latex The Product Labelling Shall Not Include:<br>- Any Term Suggesting Relative Safety, Such As Low Allergenicity, Hypoallergenicity Or Low Protein;<br>- Any Unjustified Indication Of The Presence Of Allergens; | | | X |
| e) | If The Manufacturer Labels The Gloves With The Protein Content, The Process Limit, Measured As Specified In 5.3 Shall Be Given.<br>(NOTE 2 This Does Not Allow A Protein Labelling Claim Below 50 μG/G. Lower Claims Are Not Considered To Be Reliable Given The Expected Process Variation In Manufacture And Inter-Laboratory Testing.) | | | X |

**Compliance:** The Submitted Sample **MEETS** The Requirements Of EN 455-3:2015 Clause 4.6 For Labelling.



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End of Report





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