MIPATIENT

# Product Specification Sheet.

## Nitrile Examination Gloves – Disposable.

| | |
|---|---|
| **Type** | Nitrile Examination Glove-Disposable |
| **Material** | Nitrile Butadiene Rubber (NBR) |
| **Colour** | Blue / Black |
| **Design & Feature** | Ambidextrous, Beaded Cuff, Finger Textured |
| **Donning Aid** | Chlorinated |
| **Product Classification** | FDA: 80LYY-880.6250 MDD: Class I |
| **Powder Content** | Max 2.0 milligram/glove |
| **Protein Content** | N/A |
| **Sizes Available** | S, M, L, XL |
| **Storage Condition** | Product shall be stored under room conditions, avoid direct sunlight |
| **Shelf Life** | Product shall have a shelf life of 3 years from the date of manufacture with the above storage conditions |
| **Packing Style** | Bulk Pack |
| **Performance Standard** | ASTM D6319, D6124-06, D5151-06;<br>EN ISO 374-1:2016;<br>EN ISO 374-5:2016;<br>ISO2859-1;<br>EN 374-4:2013;<br>EN 420:2003 +A1:2009;<br>EN 388:2016 +A:2018;<br>EN 455 |
| **Manufacturer Accreditations** | ISO 9001 : 2015<br>ISO 13485 : 2016 |
| **Regulatory Compliance** | MDD 93/42/ECC<br>FDA 510(k)/ Class1 |

**Glove Dimensions**

| Dimensions | Size (mm) | | | |
|---|---|---|---|---|
| | S | M | L | XL |
| Palm Width | 80 ± 10 | 90 ± 10 | 105 ± 10 | 115 ± 10 |
| Ave weight (gm) | 3.4 ± 0.3 | 3.8 ± 0.3 | 4.0 ± 0.3 | 4.3 ± 0.3 |
| Length | | Min 240 | | |
| Thickness | Cuff | 0.040 ± 0.02 | | |
| | Palm | 0.070 ± 0.02 | | |
| | Finger | 0.080 ± 0.02 | | |

**Physical Properties**

| Parameters | Before Aging | | After Aging | |
|---|---|---|---|---|
| | Force at break (N) | Elongation at break (%) | Force at break (N) | Elongation at break (%) |
| **Hanser Result** | 9.0 – 11.0 | N/A | 6.0 – 10.0 | N/A |
| **EN Requirement (median)** | Min 9 N | N/A | Min 6 N | N/A |

**Chemical Analysis**

| Requirement | Protein Content | Powder Free |
|---|---|---|
| | Powder Free | Protein Content |
| **Hanser Result** | **N/A** | **Below 2.0** |
| **ASTM requirement** | **N/A** | **Max 2.0 milligram/glove** |

**Performance**

| Inspection | Related Defects | Inspection Level | AQL |
|---|---|---|---|
| **Watertight Test** | Holes | G-1 | 1.5 |
| **Visual Inspection** | Major Defects | G-1 | 2.5 |
| | Minor Defects | S-2 | 4.0 |
| **Physical Properties** | Tensile Strength and Elongation | S-2 | 4.0 |
| **Physical Dimension** | Measurement | S-2 | 4.0 |

**REDACTED COPY – INFORMATION SHARED UPON REQUEST**

# DECLARATION OF CONFORMITY

| | | |
|---|---|---|
| Product Name | : | Nitrile Examination Gloves (Non-Sterile) |
| Type | : | Ambidextrous<br>Powder-Free<br>Black, White & Blue |
| Manufacturer's Name | : | REDACTED |
| Manufacturer's Address | : | REDACTED |
| Document No. | : | REDACTED |
| Classification | : | Class I |
| Brand | : | A2Z Medicare Nitrile Examination Gloves<br>A2Z Medicare Latex Examination Gloves |

I, the undersign, hereby declare that the medical device(s) specified above conforms to the Essential Requirements listed in Annex VII of Medical Devices Directive (MDD) 93/42/ECC and bears the mark

CE

This Declaration of Conformity is valid in connection with the release document for the respective batch produced devices. The above-mentioned declaration of conformity is under the responsibility of Manufacturer.

REDACTED
RAQA Officer

REDACTED
26 June 2020

Issued to:

REDACTED

Notified Body: 2777

SATRA customer number: P1643

# EU Type-Examination Certificate

## Certificate number: REDACTED

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

**Product reference:**

PF NBR 8mil

**Description:**

Powder free Nitrile Glove, 8mil with Pattern texture available in Black, Orange, Green and Yellow colours.

**Sizes**:
Medium – 5558PF-M
Large – 5558PF-L
X-Large – 5558PF-XL
XX-Large – 5558PF-XXL

**Classification:**

| EN ISO 374-1:2016/ Type C | Level | EN 374-4: 2013 Degradation % |
|---|---|---|
| n-Heptane (J) | 2 | 27 |
| 40% Sodium Hydroxide (K) | 6 | -58.7 |
| 96% Sulphuric Acid (L) | 0 | 100.0 |

| EN ISO 374-5: 2016 | Result |
|---|---|
| Protection against bacteria and fungi | Pass |
| Protection against viruses | N/A |

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN 388:2016+A1:2018; EN ISO 374-1:2016+A1:2018

Technical reports/Approval documents:
SATRA: SPC0247447/1626/2, CHM0247460/1626/EN/B, CHM0260647/1731/EN, CHM0262288/1738/SMcD/B, SPC0262693/1740, CHM0262288/1738/SMcD/A

Signed on behalf of SATRA:

Besjana Pilinci

Quincey Brown

**Date first issued: 26/02/2020**
**Date of issue: 26/02/2020**

**Expiry date: 26/02/2025**

# TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.