



## CERTIFICATE OF CONFORMITY & CERTIFICATE OF ANALYSIS

|                    |                                            |
|--------------------|--------------------------------------------|
| Brand              | TouchNTuff®                                |
| Size(s)            | XL (9.5 - 10)                              |
| Material           | Nitrile                                    |
| Style              | 93-700                                     |
| Short Description  | Sterile Disposable Nitrile Cleanroom Glove |
| Lot Number         | 2202EV                                     |
| Batch Number       | 22027002EV                                 |
| Manufacturing Date | 2022-02                                    |
| Expiration Date    | 2025-01                                    |

### DECLARATION OF CONFORMITY

Ansell certifies that the above product is manufactured in accordance with Ansell product specifications and is in conformity with the following standards or normative documents:

| Standard/Normative Document    | Result   |
|--------------------------------|----------|
| FDA 21 CFR 177-2600            | Conforms |
| Free from BSE/TSE (EMA/410/01) | Conforms |
| ISO 11137-1                    | Conforms |
| PPER (EU) 2016/425             | Conforms |
| Reach Regulation               | Conforms |

### DECLARATION OF ANALYSIS

| Property                                                    | Test Method        | Specification | Result   |
|-------------------------------------------------------------|--------------------|---------------|----------|
| Freedom from Holes - Final Release                          | EN455-1/ASTM D5151 | G1, AQL 1.5   | Conforms |
| Dimension Test                                              | ASTM D3767         | S-2, AQL 4.0  | Conforms |
| Glove Length (mm)                                           | ASTM D3767         | Min. 300      | Conforms |
| Palm Thickness (mm)                                         | ASTM D3767         | 0.11-0.15     | Conforms |
| Finger Thickness (mm)                                       | ASTM D3767         | 0.14–0.20     | Conforms |
| Physical Properties                                         | ASTM D412          | S-2, AQL 4.0  | Conforms |
| Tensile Strength (MPa)                                      | ASTM D412          | Min. 14       | Conforms |
| Ultimate Elongation (%)                                     | ASTM D412          | Min. 500      | Conforms |
| Liquid Particle Count 0.5-20 µ (particles/cm <sup>2</sup> ) | IEST-RP-CC005.4    | < 1200        | Conforms |
| Aluminium Al <sup>3+</sup> (µg/cm <sup>2</sup> )            | IEST-RP-CC005.4    | <0.050        | Conforms |
| Calcium Ca <sup>2+</sup> (µg/cm <sup>2</sup> )              | IEST-RP-CC005.4    | <0.500        | Conforms |
| Chloride Cl <sup>-</sup> (µg/cm <sup>2</sup> )              | IEST-RP-CC005.4    | <0.600        | Conforms |
| Copper Cu <sup>2+</sup> (µg/cm <sup>2</sup> )               | IEST-RP-CC005.4    | <0.050        | Conforms |
| Iron Fe <sup>3+</sup> (µg/cm <sup>2</sup> )                 | IEST-RP-CC005.4    | <0.050        | Conforms |
| Lithium Li <sup>+</sup> (µg/cm <sup>2</sup> )               | IEST-RP-CC005.4    | <0.0004       | Conforms |

Ansell, ® and ™ are trademarks owned by Ansell Limited or one of its affiliates. US Patented and US and non-US Patents Pending:  
[www.ansell.com/patentmarking](http://www.ansell.com/patentmarking) © 2020 Ansell Limited. All Rights Reserved.



| Property                                                      | Test Method     | Specification  | Result         |
|---------------------------------------------------------------|-----------------|----------------|----------------|
| Magnesium Mg <sup>2+</sup> (µg/cm <sup>2</sup> )              | IENT-RP-CC005.4 | <0.050         | Conforms       |
| Nitrate NO <sub>3</sub> <sup>-</sup> (µg/cm <sup>2</sup> )    | IENT-RP-CC005.4 | <0.8           | Conforms       |
| Potassium K <sup>+</sup> (µg/cm <sup>2</sup> )                | IENT-RP-CC005.4 | <0.050         | Conforms       |
| Protein Content (µg/g)                                        | EN 455-3        | Not applicable | Not applicable |
| Silicone, Amide, DOP - FTIR                                   | IENT-RP-CC005.4 | Not detectable | Conforms       |
| Sodium Na <sup>+</sup> (µg/cm <sup>2</sup> )                  | IENT-RP-CC005.4 | <0.500         | Conforms       |
| Sulphate SO <sub>4</sub> 2 <sup>-</sup> (µg/cm <sup>2</sup> ) | IENT-RP-CC005.4 | <0.200         | Conforms       |
| Zinc Zn <sup>2+</sup> (µg/cm <sup>2</sup> )                   | IENT-RP-CC005.4 | <0.300         | Conforms       |

Electronically Signed by:

**Amy Jones**

Manager, QA

Date: 8 August 2024

For additional information visit us at [www.ansell.com](http://www.ansell.com), or call us at:

**Europe, Middle East & Africa Region**

Ansell Healthcare Europe N.V.

T: +32 (0) 2 528 74 00

F: +32 (0) 2 528 74 01

**Australia**

Ansell Limited

T: +61 1800 337 041

F: +61 1800 803 578

**Latin America & Carribean Region**

Ansell Commercial Mexico S.A. de C.V.

T: +52 442 248 1544 / 248 3133

**North America Region**

Ansell Healthcare products LLC

T: +1 800 800 0444

F: +1 800 800 0445

**Asia Pacific Region**

Ansell Global Trading Center

(Malaysia) Sdn Bhd

T: +603 8310 6688

F: +603 8310 6699