

## DECLARACIÓN UE DE CONFORMIDAD EU DECLARATION OF CONFORMITY

| DECLARACION UE DE CONFORMIDAD EU DECLARATION OF CONFORMITY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                       |                                                                                     |
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| REGLAMENTO (UE)2016/425 relativo a los EPI REGULATION (EU)2016/425 concerning PPE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                       |                                                                                     |
| <b>Fabricante / Manufacturer:</b><br><br><b>SANICEN S.A.U</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Dirección / Address</b><br><b>C/ VELÁZQUEZ S/N POL. IND.</b><br><b>"MARIOLA" 45511 HUECAS – TOLEDO</b>                                                                                                                             |  |
| <p>Esta declaración de conformidad se emite bajo la exclusiva responsabilidad del fabricante, que declara que el producto:</p> <p><i>This declaration of conformity is issued under the sole responsibility of the manufacturer, who declares that the product:</i></p> <p><b>NOMBRE / NAME:</b> GUANTE DE NITRILO N1 PLUS: NITRILO AZUL SIN POLVO SENSITIVE SANYC PARA EXAMEN Y SU VARIANTE DE COLOR / <i>NITRILE GLOVE N1 PLUS: POWDER-FREE BLUE NITRILE SENSITIVE SANYC FOR EXAMINATION AND ITS COLOUR VARIANT</i></p> <p><b>CLASIFICACIÓN / CLASSIFICATION:</b> EPI Categoría III / <i>PPE Category III</i></p> <p><b>CARACTERÍSTICAS / CHARACTERISTICS:</b> Ajustable, Desechable, Color Azul / <i>Adjustable, Disposable, blue color.</i></p> <p>Presenta conformidad con lo dispuesto en el Reglamento (UE) 2016/425 del Parlamento Europeo y del Consejo de 9 de marzo de 2016 relativo a los equipos de protección individual de conformidad con el anexo IX.</p> <p><i>Conforms to Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment in accordance with Annex IX.</i></p> <p><b>Normas armonizadas aplicables editadas por el Comité Europeo de Normalización:</b><br/> <i>Applicable harmonised standards issued by the European Committee for Standardisation:</i></p> <ul style="list-style-type: none"> <li>EN 420:2003+A1:2009 y EN ISO 21420:2020</li> <li>EN ISO 374-1:2016+EN ISO 374-1:2016/A1:2018</li> <li>EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN 374-4:2013</li> <li>EN ISO 374-5:2016</li> <li>ISO 16604:2004</li> </ul> <p>El EPI objeto de esta declaración es idéntico al que ha sido sometido al examen UE de Tipo (módulo B) por el organismo notificado AITEX (Nº 0161), el cual, ha expedido el certificado de examen UE de tipo 19/1222/06/0161.</p> <p><i>The PPE covered by this declaration is identical to that which has undergone EU type-examination (module B) by the notified body AITEX (No. 0161), which has issued the EU type-examination certificate 19/1222/06/0161.</i></p> <p>El EPI de CAT. III objeto de esta declaración está sujeto al procedimiento de evaluación de la conformidad basada en el control interno de la producción más control supervisado de los productos a intervalos aleatorios (módulo C2), que garantiza la conformidad del tipo descrito en el certificado de examen UE de tipo con los requisitos aplicables al Reglamento (UE) 2016/425 bajo la supervisión del organismo notificado AITEX (Nº 0161).</p> <p><i>CAT. III PPE covered by this declaration is subject to the conformity assessment procedure based on internal production control plus supervised product checks at random intervals (module C2), which ensures conformity of the type described in the EU-type examination certificate with the requirements applicable to Regulation (EU) 2016/425 under the supervision of the notified body AITEX (No 0161).</i></p> <p><b>FECHA: Huecas, 07-julio-2025 Date: Huecas, 07<sup>th</sup> july 2025</b></p> |                                                                                                                                                                                                                                       |                                                                                     |
| <br><small>P. I. Mariola - C/ Velázquez s/n<br/>45511 Huecas (Toledo) SPAIN<br/>Tf: 925 78 44 59 - Fax: 925 78 45 02<br/>www.sanicen.com</small>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <br><small>P. I. Mariola - C/ Velázquez s/n<br/>45511 Huecas (Toledo) SPAIN<br/>Tf: 925 78 44 59 - Fax: 925 78 45 02<br/>www.sanicen.com</small> |                                                                                     |
| <b>D. ENRIQUE FERNANDEZ -ECHEVARRÍA</b><br><b>Director General / General Manager</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>DÑA. Mª PILAR MANTERO BARRANCO</b><br><b>Responsable Técnico / Technical Manager</b>                                                                                                                                               |                                                                                     |

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| REGLAMENTO (UE)2017/745 sobre productos sanitarios REGULATION (EU)2017/745 medical devices                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             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| <b>Fabricante / Manufacturer:</b><br><br><b>SANICEN S.A.U</b><br><b>SRN: ES-MF- 000000738</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Dirección / Address</b><br><b>C/ VELÁZQUEZ S/N POL. IND. "MARIOLA"</b><br><b>45511 HUECAS – TOLEDO</b>                                                                                                            |  |      |                         |        |     |                                                                    |               |     |                                                                   |               |     |                                                                   |               |     |                                                                   |               |     |                                                                    |               |                                                                                                                                                                                                                    |                                                                                                                                                                                                                      |                                                                                      |                                                                                         |
| <p>Esta declaración de conformidad se emite bajo la exclusiva responsabilidad del fabricante, que declara que el producto:</p> <p><i>This declaration of conformity is issued under the sole responsibility of the manufacturer, who declares that the product:</i></p> <p><b>NOMBRE / NAME:</b> GUANTE DE NITRILO AZUL SIN POLVO SANYC PARA EXAMEN Y SU VARIANTE DE COLOR / POWDER-FREE BLUE NITRILE SENSITIVE SANYC FOR EXAMINATION AND ITS COLOUR VARIANT<br/> <b>UDI-DI BÁSICO / BASIC UDI-DI:</b> 8431026Gloves/N/SP/EXJT<br/> <b>CÓDIGO EMDN / EMDN Code:</b> TO1020204<br/> <b>CLASIFICACIÓN / CLASSIFICATION:</b> Clase 1, reglas 1 y 5 / Class 1, rules 1 and 5<br/> <b>CARACTERÍSTICAS / CHARACTERISTICS:</b> Ajustable, Desechable, Color Azul / Adjustable, Disposable, blue color.</p> <table border="1"> <thead> <tr> <th>REF.</th> <th>DESCRIPCIÓN DESCRIPTION</th> <th>UDI-DI</th> </tr> </thead> <tbody> <tr> <td>270</td> <td>GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. XS</td> <td>8431026002709</td> </tr> <tr> <td>271</td> <td>GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. S</td> <td>8431026002716</td> </tr> <tr> <td>272</td> <td>GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. M</td> <td>8431026002723</td> </tr> <tr> <td>273</td> <td>GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. L</td> <td>8431026002730</td> </tr> <tr> <td>274</td> <td>GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. XL</td> <td>8431026002747</td> </tr> </tbody> </table> <p>Es conforme con los requisitos generales de seguridad y funcionamiento y disposiciones establecidas por el Reglamento (UE) 2017/745 del Parlamento Europeo y del Consejo de 5 de abril de 2017 sobre los Productos Sanitarios en cumplimiento del artículo 19, y del Real Decreto 192/2023, de 21 de marzo, por el que se regulan los productos sanitarios, por lo que queda garantizada la ausencia de compromiso para la salud y la seguridad de las personas, siempre que el producto se utilice conforme a su finalidad prevista, así como que ofrece las prestaciones asignadas.</p> <p><i>It complies with general safety and performance requirements established by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices in compliance with Article 19, and Royal Decree 192/2023 of 21 March, which regulates medical devices, so that the absence of compromise to the health and safety of persons is guaranteed, provided that the product is used in accordance with its intended purpose, as well as that it offers the assigned performance.</i></p> <p><b>FINALIDAD PREVISTA:</b> Reducir el riesgo de infección y/o contaminación.<br/> <b>INTENDED PURPOSE:</b> To reduce the risk of infection and/or contamination.</p> <p>Normas armonizadas aplicables utilizadas / Applicable harmonised standards used:</p> <ul style="list-style-type: none"> <li>EN 455-1</li> <li>EN 455-2</li> <li>EN 455-3</li> <li>EN 455-4</li> </ul> <p><b>FECHA:</b> Huecas, 07-julio-2025 <b>Date:</b> Huecas, 07<sup>th</sup> july 2025</p> <table border="1"> <tr> <td> <br/> P. L. Mariola - C/ Velázquez s/n<br/> 45511 Huecas (Toledo) SPAIN<br/> Tf.: 925 78 44 59 - Fax: 925 78 45 02<br/> www.sanicen.com </td> <td> <br/> P. L. Mariola - C/ Velázquez s/n<br/> 45511 Huecas (Toledo) SPAIN<br/> Tf.: 925 78 44 59 - Fax: 925 78 45 02<br/> www.sanicen.com </td> </tr> <tr> <td> <b>D. ENRIQUE FERNANDEZ -ECHEVARRÍA</b><br/> <b>Director General / General Manager</b> </td> <td> <b>DÑA. Mª PILAR MANTERO BARRANCO</b><br/> <b>Responsable Técnico / Technical Manager</b> </td> </tr> </table> |                                                                                                                                                                                                                      |                                                                                     | REF. | DESCRIPCIÓN DESCRIPTION | UDI-DI | 270 | GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. XS | 8431026002709 | 271 | GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. S | 8431026002716 | 272 | GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. M | 8431026002723 | 273 | GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. L | 8431026002730 | 274 | GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. XL | 8431026002747 | <br>P. L. Mariola - C/ Velázquez s/n<br>45511 Huecas (Toledo) SPAIN<br>Tf.: 925 78 44 59 - Fax: 925 78 45 02<br>www.sanicen.com | <br>P. L. Mariola - C/ Velázquez s/n<br>45511 Huecas (Toledo) SPAIN<br>Tf.: 925 78 44 59 - Fax: 925 78 45 02<br>www.sanicen.com | <b>D. ENRIQUE FERNANDEZ -ECHEVARRÍA</b><br><b>Director General / General Manager</b> | <b>DÑA. Mª PILAR MANTERO BARRANCO</b><br><b>Responsable Técnico / Technical Manager</b> |
| REF.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   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| 271                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. S                                                                                                                                                    | 8431026002716                                                                       |      |                         |        |     |                                                                    |               |     |                                                                   |               |     |                                                                   |               |     |                                                                   |               |     |                                                                    |               |                                                                                                                                                                                                                    |                                                                                                                                                                                                                      |                                                                                      |                                                                                         |
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| 273                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. L                                                                                                                                                    | 8431026002730                                                                       |      |                         |        |     |                                                                    |               |     |                                                                   |               |     |                                                                   |               |     |                                                                   |               |     |                                                                    |               |                                                                                                                                                                                                                    |                                                                                                                                                                                                                      |                                                                                      |                                                                                         |
| 274                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | GUANTE DE NITRILO AZUL SIN POLVO SANYC SENSITIVE – 100 UDS – T. 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| <b>D. ENRIQUE FERNANDEZ -ECHEVARRÍA</b><br><b>Director General / General Manager</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>DÑA. Mª PILAR MANTERO BARRANCO</b><br><b>Responsable Técnico / Technical Manager</b>                                                                                                                              |                                                                                     |      |                         |        |     |                                                                    |               |     |                                                                   |               |     |                                                                   |               |     |                                                                   |               |     |                                                                    |               |                                                                                                                                                                                                                    |                                                                                                                                                                                                                      |                                                                                      |                                                                                         |