SANICEN S.A.U.

- Guantes y Equipos de Protección Individual
- División Profesional
- División Consumo
- División Sanitaria

EU DECLARATION OF CONFORMITY

EU Regulation 2017/745 for Medical Devices (Class I)

EU Regulation 2016/425 on Personal Protective Equipment (Cat III)

MANUFACTURER:	*SANICEN S.A.U.*
SINGLE REGISTRATION NUMBER (SRN):	*ES-MF-000000738*
ADDRESS:	*C/ VELÁZQUEZ S/N* *POL. IND. "MARIOLA"* *45511 HUECAS -TOLEDO-*

CE

This declaration of conformity is issued under the sole responsibility of the manufacturer and declares that the product:

NAME:	*GUANTE LATEX L2 Y SUS VARIANTES*
BRAND:	*RĘKAWICE DIAGNOSTYCZNE LATEKSOWE PUDROWANE APTECZKA ABC*
CLASSIFICATION:	*MD Class I non sterile / PPE Category III*
UDI-DI BASIC:	*5902666Gloves/L/CP/EXVT*
FAMILY:	*LATEX DISPOSABLE GLOVES*
CHARACTERISTICS:	*HYGIENIC (U.S.U) / ADJUSTABLE / DISPOSABLE / NATURAL COLOUR*

REFERENCE	*SIZE*	*UDI-DI*
650043	*S*	*5902666653628*
650044	*M*	*5902666653611*
650045	*L*	*5902666653604*

It is in accordance with the 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 1591/2009, of October 16, by which medical devices are regulated, so the absence of commitment to the health and safety of people is guaranteed, provided that the product is used according to its intended purpose, as well as that it offers the assigned benefits.

It complies with the provisions of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment in compliance with annex IX

INTENDED PURPOSE: To reduce the risk of infection and/or contamination

Applicable harmonized standards used;

MEDICAL DEVICES	*PERSONAL PROTECTIVE EQUIPMENT*
EN 455-1	*EN 420:2003+A1:2009*
EN 455-2	*EN ISO 374-1:2016/A1:2018*
EN 455-3	*(EN 374-2:2020, EN 16523-1:2015+A1:2018, EN 374-4:2019)*
	EN ISO 374-5:2016 (ISO 16604:2004)

Additionally, the product is identical to the one that has undergone EU type examination (module B), which is referred to in certificate No. 19/1030/02/0161 issued by the notified body AITEX (No. 0161).

The PPE of Cat. III is subject to the conformity assessment procedure based on internal production control plus supervised control of products at random intervals (module C2), under the supervision of the Notified Body AITEX (No. 0161).

DATE: Huecas, 12-August-2022

CARLOS TENORIO HERNÁNDEZ — *Managing Director*

SANICEN S.A.U. Polígono Industrial "Mariola" c/ Velázquez, s/n. 45511 HUECAS (Toledo) SPAIN Tlf.: 925 78 44 59 Fax: 925 78 45 02

Mª PILAR MANTERO — *Technical Manager*

SANICEN S.A.U.

Fábrica y Oficina
Tlfns(+34) 925 78 44 59 (+34) 925 78 44 78 (+34) 925 78 41 37
Fax: (+34) 925 78 45 02 Fax: (+34) 925 73 04 64
E-mail: info@sanicen.com · www.sanicen.com
C/. Velázquez, s/n Polígono Industrial Mariola 45511 Huecas (Toledo)
Apdo. de Correos 72, 45510 Fuensalida (Toledo) SPAIN