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*

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

NAME:	*GUANTE LATEX L1: LATEX SIN POLVO NEW MARK PARA EXAMEN*
BRAND:	*RĘKAWICE DIAGNOSTYCZNE LATEKSOWE BEZPUDROWE APTECZKA ABC*
CLASSIFICATION:	*MD Class I non sterile / PPE Category III*
UDI-DI BASIC:	*5902666Gloves/L/SP/EX3E*
FAMILY:	*LATEX DISPOSABLE GLOVES*
CHARACTERISTICS:	*HYGIENIC (U.S.U) / ADJUSTABLE / DISPOSABLE / NATURAL COLOR*

REFERENCE	*SIZE*	*UDI-DI*
650040	*S*	*5902666653581*
650041	*M*	*5902666653574*
650042	*L*	*5902666653567*

It is in accordance with the requirements of 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 2016, 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

Relevant harmonised standards used:

MEDICAL DEVICES	*PERSONAL PROTECTIVE EQUIPMENT*
EN 455-1	*EN 420:2003+A1:2009 and EN ISO 21420:2020*
EN 455-2	*EN ISO 374-1:2016/A1:2018*
EN 455-3	*(EN 374-2:2014, EN 16523-1:2015+A1:2018, EN 374-4:2013)*
	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. 19/1236/02/0161 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, 13-July-2022

CARLOS TENORIO HERNÁNDEZ

Managing Director

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