

DECLARATION OF CONFORMITY UE

MANUFACTURER: **Itano Spółka z ograniczoną odpowiedzialnością**
ul. Szparagowa 14
52-311 Wrocław, Poland

under the sole responsibility declares that the nitrile, powder-free, non-sterile, examination and protective disposable gloves:

ITANO BLACK
(List of available models in Annex 1)

Basic UDI-DI code: 5903631588 NE PF N 9F

meet the applicable requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

The product, in accordance with Annex VIII of Regulation 2017/745, has been classified as a Class I medical device, according to Rule 5.

In order to demonstrate the safety and effectiveness of the medical device the following standards were used for the conformity assessment:

EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 20417:2021, ISO 2859, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 21171:2006

AND

meets the applicable requirement of Regulation (EU) 2016/425 of the European Parliament and Council of 9 March 2016 on personal protective equipment.

The product, in accordance with Annex I of Regulation (EU) 2016/425, has been classified as a category III personal protective equipment.

In order to demonstrate the safety and effectiveness of the medical device and personal protective equipment, the following standards were used for the conformity assessment:

EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN 374-2:2014, EN 374-4:2019, EN ISO 374-5:2016, EN 16523-1:2015+A1:2018

Notified body under number 2777, Satra Technology Europe Ltd, Bracetown Business Park Clonee, Dublin, Ireland, carried out the EU type examination (module B) and issued the EU type examination certificate number UE 2777/10015-05/E02-01.

PPE Category III product is subject to the type conformity assessment procedure based on internal production control and supervised product checks at randomly selected intervals (module D), under the supervision of the notified body number 2797, BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands.

Revision: 1

Approver:

Valid from: 11.05.2022

Leszek Michnowski

Place: Wrocław, Poland

Stamp & signature:


ITANO
ITANO Sp. z o.o.
Leszek Michnowski
Prezes Zarządu

Annex 1 to the EU declaration of conformity

List of available models of the product: nitrile, powder-free, non-sterile, examination and protective disposable gloves:

brand	Reference No.	size	Quantity per package	UDI – DI code (EAN)- '- unit package	EAN code – collective package
Itano BLACK	EG02XS	XS (5-6)	100 szt.	5903631588051	5903631588204
	EG02S	S (6-7)	100 szt.	5903631588068	5903631588211
	EG02M	M (7-8)	100 szt.	5903631588075	5903631588228
	EG02L	L (8-9)	100 szt.	5903631588082	5903631588235
	EG02XL	XL (9-10)	100 szt.	5903631588099	5903631588242

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