

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 BASIC
(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 2777/10015-05/E03-01.

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 C2), under the supervision of the notified body number 2777, Satra Technology Europe Ltd, Bracetown Business Park Clonee, D15 YN2P Dublin, Ireland.

Revision: 1

Approver:

Valid from: 03.03.2022

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 BASIC	EG01XS	XS (5-6)	100 szt.	5903631588006	5903631588150
	EG01S	S (6-7)	100 szt.	5903631588013	5903631588167
	EG01M	M (7-8)	100 szt.	5903631588020	5903631588174
	EG01L	L (8-9)	100 szt.	5903631588037	5903631588181
	EG01XL	XL (9-10)	100 szt.	5903631588044	5903631588198

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