

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 PRO
(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 1041:2008+A1:2013, ISO 2859, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2013, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, 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, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016, EN 16523-1:2015, ISO 16604:2004

Notified body under number 2777, Satra Technology Europe Ltd, Bracetown Business Park Clonee, Dublin 15, Dublin, Ireland, carried out the EU type examination (module B) and issued the EU type examination certificate number 2777/11581-02/E07-01.

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, Dublin 15, Dublin, Ireland.

Revision: 2

Approver:

Valid from: 22.06.2021

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 PRO	EG08XS	XS (5-6)	100 szt.	5903631588624	5903631588679
	EG08S	S (6-7)	100 szt.	5903631588631	5903631588686
	EG08M	M (7-8)	100 szt.	5903631588648	5903631588693
	EG08L	L (8-9)	100 szt.	5903631588655	5903631588709
	EG08XL	XL (9-10)	100 szt.	5903631588662	5903631588716

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Leszek Michnowski
Przewodniczący Zarządu