EU Declaration of Conformity

Manufacturer: Medasept S.A. ul. Forteczna 19; 61-362 Poznań.

We declare under our sole Responsibility that the following product:

Trade Name:	Nitrile Examination Gloves Powder Free, Non Sterile
Product Name:	**medaSEPT NITRILE PREMIER PF**
Product Code:	MSNPRPF100/ MSNPRPF200
Size:	XS, S, M, L, XL
Packaging Style:	100 pcs /200 pcs
Class of Risk:	MDR- Class I , Rule 5
	PPE- Category III

Basic UDI-DI: 590173887RDNPFLG

covered by this declaration of conformity meets the requirement of:

- Regulation of the European Parliament and of the Council (EU) 2017 /745 of April 5, 2017 [MDR]

Conformity assessment procedure conducted in accordance with Annexes I+IV

List of applicable standards harmonized with the requirements of the Regulation of the European Parliament and of the Council (EU) 2017 /745 of April 5, 2017 [MDR]:

EN 15223 -1, EN 1041, EN ISO 14971, EN ISO 13485EN ISO 10993-1;5,10, EN 455 -1;2;3;4

- Regulation of the European Parliament and of the Council (EU) 2016/425 of March 9, 2016 r. [PPE]

List of applicable standards harmonized with the requirements of the Regulation of the European Parliament and of the Council (EU) 2016/425 of March 9, 2016 r. [PPE]:

EN 420: 2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013,

EN ISO 374-5:2016

For the product as a PPE, the EU-type examination (module B) was carried out by a notified body

SATRA Technology Europe Limited (2777)

Bracetown Business Park, Clonee D15 YN2P, Ireland

The product, as PPE, is subject to a type conformity assessment procedure based on internal production control and supervised product checks at random intervals (Module C2), under the supervision of the notified body 2777.

Poznań, dnia 01.03.2021 r.

Podpis w imieniu producenta:

Dyrektor ds. Zakupów i Produktów
Jowita Bonca-Szymańska
Purchasing & Product Director

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