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 PRIME PF**
Product Code:	MSNPMPF100/MSNPMPF200
Size:	XS, S, M, L, XL
Packaging Style:	100/200 pcs
Class of Risk:	MDR- Class I , Rule 5
	PPE- Category I

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

Conformity assessment procedure conducted in accordance with Annexes I+IV of the Regulation of the European Parliament and of the Council (EU) 2017 /745 of April 5, 2017 [MDR]

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

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

Poznań, 01.03.2021 r.

Signature on behalf of the Manufacturer:

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

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