

## 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: Vinyl Examination Gloves Powder Free, Non Sterile  
Product Name: **medaSEPT vinyl PF**  
Product Code: MSVPF100  
Size: XS, S, M, L, XL  
Packaging Style: 100 pcs  
Class of Risk: MDR- Class I , Rule 5  
PPE- Category I

Basic UDI-DI: 590173887RDVPFMQ

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, dnia 01.03.2021 r.

Signature on behalf of the Manufacturer:

**Medasept Spółka Akcyjna**

ul. Forteczna 19, 61-362 Poznań  
NIP 7822557229, REGON 302347543  
tel./fax +48 67 263 34 81  
Biuro Zarządu

<sup>(6)</sup> Al. Powstańców Wlkp. 12, 64-920 Piła

Dyrektor ds. Zakupów i Produktów

Jowita Boryda-Szymalska  
Purchasing & Product Director