



## EU DECLARATION OF CONFORMITY



**Manufacturer:** MONDO Sp. z o.o.  
Ul. Katowicka 139  
43-346 Bielsko -Biala  
Poland

hereby declare on its own sole responsibility that :

### **Disposable nitrile gloves ESSENTI CARE in blue colour**

meets the requirement of Medical Device Regulation ( EU) 2017/745 of 5<sup>th</sup> of April 2017 on medical devices.

The product is in conformity with the requirements of Annex VIII Medical Device Regulation (EU) 2017/745, has been classified as a class I medical device, according to the rule 1.

In order to demonstrate safety and effectiveness of a medical device, the applicable standards for conformity assessment applied as follows: EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009, EN ISO 13485:2016

and

product meets the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9<sup>th</sup> March 2016 on Personal Protective Equipment.

The product, in accordance with Annex I of the Regulation (EU) 2016/425 has been classified as personal protective equipment category I.

In order to demonstrate safety and effectiveness of personal protective equipment, for conformity assessment applied as follows: EN 420:2003+A1:2009, EN ISO 9001: 2015

Version: 3

Valid from: 07.10.2019

Place of issue: Bielsko -Biala

Name and surname of authorised person:

Piotr Trzepaczka

Stamp and signature:

MONDO Sp. z o.o.  
PREZES ZARZADU  
*Piotr Trzepaczka*

**Piotr Trzepaczka**

**MONDO**

Spółka z ograniczoną odpowiedzialnością  
43-346 Bielsko-Biala, ul. Katowicka 139  
NIP 5472134880 REGON 241940110  
KRS 0000386563

## EU DECLARATION OF CONFORMITY

**Manufacturer:** **MONDO Sp. z o.o.**  
**Ul. Katowicka 139**  
**43-346 Bielsko Biala**  
**Poland**

declares on its sole responsibility that the products:

**Disposable nitrile gloves ESSENTI CARE**  
**in blue colour**

meet applicable requirements::

- Regulation (EC) No 1935/2004 of the European Parliament and of the Council concerning the materials and articles intended to come into contact with food.
- Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
- EC Regulation 2023/2006 on good manufacturing practices in regards to materials and articles intended to come into contact with food.

The products to which this declaration relates meet the limits of the global migration level, not exceeding the level of 10mg/ dm<sup>2</sup>.

The products can be used in contact with all types of food, including fatty, acidid and alcohol-containing foods.

Products stores in accordance with the manufacturer's recommendations and used in normal or foreseeable conditions do not pose a threat to human health, do not cause unacceptable changes in the composition of the food and do not deteriorate the organoleptic properties of food.

Version: 1

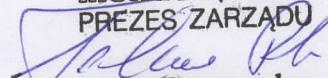
Valid from: 07.10.2019

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**Mondo Sp. z o.o.**  
**PREZES ZARZADU**  
  
**Piotr Trzepaczka**