



ESSENTI CARE

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 SAFE

meets the requirement of Medical Device Regulation (EU) 2017/745 of 5th 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 and 5.

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

Basic UDI-DI: 590240949nitrileglovesBA

ESSENTI CARE SAFE rozmiar S: 5902409493962

ESSENTI CARE SAFE rozmiar M: 5902409493979

ESSENTI CARE SAFE rozmiar L: 5902409493986

ESSENTI CARE SAFE rozmiar XL: 5902409493993

Version: 2

Valid from: 23.06.2021

Place of issue: Bielsko -Biala

Name and surname of authorised person:

Piotr Trzepaczka

Stamp and signature:

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