

DECLARATION OF COMPLIANCE

1. Data of the issuer of the declaration and the manufacturer of the product:
Mercator Medical S.A.
ul. H. Modrzejewskiej 30,
31-327 Kraków, Poland
2. Product identification data:
nitrylex one by one
powder-free, nitrile, blue, examination and protective gloves, non-sterile, single use, made of **nitrile**
(*acrylonitrile butadiene rubber*)
3. Date of issue:
24.09.2025
4. Based on the tests performed, we declare that above listed product meets the requirements of the following legislation:
 - Regulation (EC) No 1935/2004 (with amendments) on materials and articles intended to come into contact with food from 27 October 2004 and repealing Directives 80/590/EEC and 89/109/EEC, including Articles 3, 11(5), 15 and 17;
 - Commission Regulation (EC) No 2023/2006 (with amendments) on good manufacturing practices for materials and articles intended to come into contact with food from 22.12.2006;
 - Commission Regulation (EU) No 10/2011 (with amendments) from 14 January 2011 on plastic materials and articles intended to come into contact with food;
5. Information on substances with a specific migration limit according to Commission Regulation (EU) No. 10/2011:
 - No substances for which limits are specified in Annex I to Commission Regulation (EU) No. 10/2011 were used in the product;
 - No substances of very high concern (SVHC) listed on the candidate list published on the website of the European Chemicals Agency were used in the product;
 - The specific migration of substances specified in Annex II to Commission Regulation (EU) No 10/2011 do not exceed the defined limits;
6. The type or types of food the product may come into contact with:
All types of food (in accordance with the requirements of Annex III, Table 3 of Commission Regulation 10/2011).

Time and temperature of processing and storage in contact with food:
30 min at 40°C (room temperature or lower- according to Annex V, Table 3 of Commission Regulation 10/2011).
7. The product is not intended for reprocessing.
8. The product has not been manufactured with substances that have been manufactured from waste.

Legal disclaimers: This declaration of conformity is valid at the time of issuance until Mercator Medical S.A. publishes a new version of the declaration.

Date: 24.09.2025

Signed on behalf of the Manufacturer:



Leszek Garbacz
Regulatory and Documentation Manager
PRRC