MERCATOR

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 black
   powder-free, nitrile, black, 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