

Dated: 21st February, 2026

Declaration of Conformity: Medical Device Regulation (EU) 2017/745 and Personal Protective Equipment Regulation (EU) 2016/425

We, **Innovative Gloves Company Limited**, hereby declare under our sole responsibility that all **Latex Examination and Disposable Gloves** supplied by us comply with all applicable provisions and essential requirements of the relevant European Union legislation and standards.

Applicable EU Legislation and Standards

1. Medical Device Regulation (EU) 2017/745 (MDR):

The required conformity assessment procedures in accordance with MDR Annexes I, II, and III have been performed, and the technical documentation is maintained and available.

2. Personal Protective Equipment Regulation (EU) 2016/425 of the European Parliament and of the Council:

The required conformity assessment procedures in accordance with the PPE Regulation for Category III PPE have been performed, and the technical documentation is maintained and available.

Medical Device Classification

- Medical Device Class: Class I, according to Rules 1 and 5 of MDR Annex VIII
- UMDNS: 11882
- GMDN: 34020
- EMDN: T010201

EUDAMED Registered Basic UDI-DI for Nitrile Examination Gloves: 970011054734020AA

Innovative Gloves Company Limited – EUDAMED SRN: TH-MF-000029347

European Authorized Representative (MDR Only)

The European Authorized Representative for Innovative Gloves Company Limited is:

Advena Limited

Tower Business Centre, 2nd Floor, Tower Street

Swatar, BKR 4013, Malta

SRN: MT-AR-000000234

(Applicable for MDR only)

Basis of Declaration (MDR)

This Declaration of Conformity is issued in accordance with Annex IV of the Medical Device Regulation (EU) 2017/745, based on compliance with:

- Quality Management System certification to EN ISO 13485:2016, under the supervision of TÜV SÜD America Inc.
Certificate No.: QS2 086222 0005 Rev.03

PPE Regulation Compliance

For the purposes of the PPE Regulation, the object of this declaration is in conformity with the following harmonised standards:

- EN ISO 21420:2020
- EN 455-1:2020
- EN 455-2 & EN 455-3:2015
- EN 455-4:2009
- EN ISO 374-1:2016 + A1:2018
- EN ISO 374-2:2019
- EN 16523-1:2015 + A1:2018
- EN ISO 374-4:2019
- EN ISO 374-5:2016

The products also comply with ASTM D6319 and ASTM D5151 standards.

Food Contact Compliance

The gloves are suitable for food contact applications and comply with:

- EN 1186
 - Regulation (EU) No. 10/2011
 - Regulation (EC) No. 1935/2004

- US FDA 21 CFR 177.2600 (e) and (f)

Notified Body

The notified body for PPE conformity assessment is:

SATRA Technology Europe Ltd., Ireland

Notified Body Number: **2777**

SATRA performs ongoing EU conformity surveillance (Module C2) and has issued EU Type Examination Certificates (Module B) for **Category III PPE** covering all latex glove types manufactured by Innovative Gloves Company Limited.

This declaration is issued in good faith based on current supplier information, raw material data, and internal manufacturing practices.

Authorized by:

Name: Vishesh Sood

Title: Director

Company: Innovative Gloves Co., Ltd



Signature

Date: 21/2/2026

Validity of this Declaration: 21/2/2029
