

Dated: 21<sup>st</sup> 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 **Nitrile 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: 56286
- EMDN: T01020204

EUDAMED Registered Basic UDI-DI for Nitrile Examination Gloves: 970021054656286D8

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 nitrile glove types manufactured by Innovative Gloves Company Limited, including:

- Diamond Textured Gloves
- Lite & Soft Gloves
- Five-Finger Textured Gloves
- Gripper Textured Gloves
- Biodegradable Nitrile Gloves

Available in various colours.

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

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**Authorized by:**

Name: Vishesh Sood

Title: Director

Company: Innovative Gloves Co., Ltd.

**Signature:** 

**Date:** 21/2/2026

**Validity of this Declaration:** 21/2/2028

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