บริษัท อินโนเวทีฟ โกลฟส์ จำกัด
INNOVATIVE GLOVES CO.,LTD.

830 หมู่ 4 ถ.สนามบิน-บ้านกลาง ต.ควนลัง อ.หาดใหญ่ จ.สงขลา 90110. 830 Moo 4 Sanambin-BanKlang Rd., Kuanlang, Hatyai, Songkhla 90110 Thailand
Tel.: (6674) 502251 Fax: (6674) 502252, 474734 Email: rsood@innovativeglove.com www.innovativegloves.net

Date: 30th October'2023

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

We, at the Innovative Gloves Company Limited herewith declare and issue this declaration of conformity under our sole responsibility that all the Latex Examination and disposable Gloves supplied by us to our customers meet all the applicable provisions, especially the essential requirements of the EU legislation and standards.

The applicable EU legislation and standards are

1) MDR (EU) 2017/745. The required conformity assessment procedure according to MDR Annex I, II & III has been performed and the technical documentation is kept available.

2) PPE Regulation (EU) 2016/425 of the European Parliament and of the council on PPE Category III. The required conformity assessment procedure according to PPE regulation has been performed and the technical documentation is kept available.

Medical Device: Class 1 according to Rules 1 and 5 according to MDR Annex VIII.

UMDNS: 11882, GMDN: 34020 and EMDN: T010201
EUDAMED Registered Basic UDI-DI for Latex Exam. Glove:970011054734020AA
Innovative Glove Co. Ltd.'s EUDAMED SRN: TH-MF-000029347

EC 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)

This Declaration of Conformity is issued on the basis of fulfillment of the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745 with:

• Quality Management System certification to EN ISO 13485: 2016 under the supervision of TÜV SÜD America Inc., certificate No. QS2 086222 0005 Rev.02

บริษัท อินโนเวทีฟ โกลฟส์ จำกัด
INNOVATIVE GLOVES CO.,LTD.

830 หมู่ 4 ถ.สนามบิน-บ้านกลาง ต.ควนลัง อ.หาดใหญ่ จ.สงขลา 90110. 830 Moo 4 Sanambin-BanKlang Rd., Kuanlang, Hatyai, Songkhla 90110 Thailand
Tel.: (6674) 502251 Fax: (6674) 502252, 474734 Email: rsood@innovativeglove.com www.innovativegloves.net

For PPE regulation: The object of the declaration is in conformity with the following relevant union harmonization legislation:

- EN ISO 21420:2020.
- EN 455-1:2020, EN 455- 2&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

And compliance to ASTM D3767 and ASTM D5151standards,
Food Safe Application — Overall migration EN 1186, EN 10/2011, EC Regulation No.1935/2004 and US FDA 21 CFR 177.2600 (e) & (f)

Our notified Body is SATRA Technology Europe Ltd., Ireland (NB No.2777) and they are performing the ongoing EU-type examinations (Module C-2) and issued the EU-type (Module-B) CAT III examination certificates for our Latex Examination /disposable gloves.

(V.SARAVANAKUMAR)
Sr. Manager - Technical
Authorized Signatory

Innovative Gloves Company Limited

Validity of this Declaration until 24/01/2026