



Happy Hands Gloves Co., Ltd

43/16, Moo 1, T. Bangduen, A. Phun Phin, Surat Thani 84130, Thailand
Tel No. +6677443142, +6677443143, Fax No. +6677443144 Mobile: 0858850948, 0970323652
E MAIL: mktg@happyhandsgloves.com, rajadwivedy@live.com

Declaration of Conformity

This certificate is valid for all non-sterile medical gloves (class I) described as follows: EU Medical Device Regulation 2017/745 and in Accordance with Article 19 & Annex IV

Device Manufacturer: Happy Hands Gloves Company Limited
Management representative: Mr. Raja Babu Dwivedy
Manufacturer Address: 43/16 Moo 1, T. Bangduen,
A. Phunphin, Suratthani,84130.
Thailand.
Mobile: +66 8 58850948
Email: mktg@happyhandsgloves.com
Website: <https://happyhandglove.com>

We declare on our own responsibility that the medical device 'Latex Examination, Non-sterile, Powder Free Gloves (Polymer Coated) L-PF01 of Class I under Rule 1 and 5 according to Annex VIII meets all the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, which apply to it.

Product Name: Latex Examination, Non-sterile, Powder Free Gloves
(Polymer Coated)

Product Code: L-PF01

Device classification: Class I under Rule 1 and 5 (according to Annex VIII of the
regulation (EU) 2017/745)

SRN Of Manufacturer.: TH-MF-000014349

Basic UDI-DI (GTIN): 8859727300014

Conformity assessment procedure: Annexes II and III (As per MDR 2017/745)

GMDN code and term: 47172 Hevea-latex examination/treatment glove, non-
powdered, non-antimicrobial

EMDN/CND: T010201 (Examination/ Treatment Gloves, Latex)

**The Authorized Representative within the
EU who has been empowered to enter
into commitments on our behalf is:** MedNet EC-REP GmbH
Borkstrasse 10.
48163 Münster,
Germany

SRN of the Authorized Representative: DE-AR-000000002



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Intended Purpose: Latex examination glove is a disposable device intended for medical purposes that is worn by doctors or the medical professional to minimize contact with the patient's body fluid, blood, secretions, excretions and the associated risk of contamination from pathogens capable of reproduction and barrier as protection from biological agents to protect the patient as well as the medical examiner from cross contamination. Examination glove is intended for medical activities except surgery.

12/10/2021
(THAILAND)

Mr. Raja Babu Dwivedy
(Managing Director)