

HOLIK ASIA GROUP CO.,LTD

No.18,Nanyi Road,Xuanzhou Economic Development Zone,Liqiao Town,
Xuanzhou District,Xuancheng City,Anhui Province,China

EU DECLARATION OF CONFORMITY

Manufacturer:

HOLIK ASIA GROUP CO., LTD
No.18, Nanyi Road, Xuanzhou Economic Development Zone,
Liqiao Town, Xuanzhou District,
Xuancheng City, Anhui Province

Authorised Representative:

SRN: CZ-AR-000014367

Holik International s.r.o.

Za Dvorem 612,
763 14, Zlín 12,
Czech Republic

This declaration of conformity is issued under the sole responsibility of the manufacturer HOLIK ASIA GROUP CO., LTD.

Product identification:

Nitrile examination & protective gloves – M7001-001

Basic UDI-DI: 859406007001G9

0745110765608 - disposable nitrile gloves BLUE size S, 200 pcs
0745110765615 - disposable nitrile gloves BLUE size M, 200 pcs
0745110765622 - disposable nitrile gloves BLUE size L, 200 pcs
0745110765639 - disposable nitrile gloves BLUE size XL, 200 pcs

Disposable nitrile examination and protective gloves - Nitrile examination & protective gloves – M7001-001 are in conformity with the requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Article 3 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food. They were classified as Personal Protective Equipment - Category III and as Medical Device - Risk Class I.

The gloves fulfil the essential health and safety requirements as they are stated in the harmonized technical standards EN ISO 21420:2020, 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, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 1186-1:2002 and EN 1186-3:2002.

Intended use:

Disposable nitrile examination and protective gloves are intended to protect the user from dangerous chemicals and microorganisms and to come into contact with foodstuffs. The gloves also protect the patient and user from cross-contamination. They are intended for an individual patient in a single procedure. They are intended for examinations, diagnostic and therapeutic procedures and for handling of contaminated medical material. Its intended use is in the healthcare, industry and food industry.

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Notified Body:

Institute for Testing and Certification a.s., NB 1023

Tř. T. Bati 299,
764 21 Zlín – Louky,
Czech Republic,

performed the EU Type-Examination (Module B) and issued the EU Type-Examination Certificate No. 21 0245 T/NB
and Evaluation Report Ref. No.: 723302118/2021.

The PPE is subject to the conformity assessment procedure according Module C2 under surveillance of the Notified
Body ITC, Nr. 1023.

This Declaration of Conformity is available on web site www.holik-international.com.

In Zlín 12, 8th December 2021

汉洛科(安徽)医疗设备有限公司
HOLIK ASIA GROUP CO.,LTD



Name: Daniel Kong
Position: Director