

**RĘKAWICE NITRYLOWE DIAGNOSTYCZNE LYNCMED - DEKLARACJA ZGODNOŚCI**

EU DECLARATION OF CONFORMITY

Regulation (EU) 2016/425

Number: 001

Product: Disposable Medical Nitrile Examination Gloves

LM010101 (Blue), LM010102 (Blue Purple), LM010103  
(Cobalt Blue), LM010104 (White), LM010105 (Black)

Manufacturer: Lyncmed Medical Technology (Beijing) Co.,Ltd.;

Room 1601, Building No.2, Zhubang 2000 Busniess

Building, Chaoyang District, 100022 Beijing, China

Authorised Representatives: Lyncmed Technology SRL

Italy Milano(MI) Via Procaccini Giulio Cesare 32 Cap 20154

This declaration of conformity is issued under the sole responsibility of the  
manufacturer.Product which is object of this declaration is in conformity with PPE  
Regulation (EU) 2016/425

Standards applied: EN ISO 374-1:2016 ; EN 374-4:2013; EN ISO 374-  
5:2016; EN 420: 2003+A1: 2009

Category: III

## Conformity Assurance Procedure

Notified Body: SATRA Technology Europe Ltd.

Eu-type examination (module B) certificate no 2777/11521-01/E07-01.

Certificate of conformity to type based on quality assurance of the production process  
Module C2 by Notify Body Satra Technology Europe Ltd. , number of NB: 2777

We also declare on our own responsibility that the above product meets provisions of  
the regulation (EU) 2017/745

Standards related to the regulation (EU) 2017/745

EN ISO 13485:2016, EN ISO 14971:2019, IEC 62366-1:2020, EN ISO 15223-1:2016,  
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 1041:2008,  
EN ISO 10993-1:2018, EN ISO 10993-10:2016 , EN ISO 10993-12:2012

Class of medical device: class 1 rule 1

Classification rule: Chapter III, anex VIII, EU 2017/745

Basic UDI-DI: 697160547A1X9

Intended use:

Disposable examination nitrile gloves protect against chemical and microorganism hazards. They are used to perform medical examinations, diagnostic procedures. They are intended to be worn on your hands to protect your hands and fingers from chemical hazards. They protect the patient and user. Gloves can also be used in contact with food. The gloves are intended for single use only.

Conformity assessment procedure: Annex II + III

Beijing, 2019.7.24

周佳莉

RA Manager