



EU Declaration of Conformity
According to Medical Device Regulation (EU) 2017/745
and PPE Regulation (EU) 2016/425



For the following Equipment,

Product : **Latex Examination Gloves Lightly Powdered**
Latex Examination Gloves Powder Free
ECRI No. : 11882 (base on ECRI Universal Medical Device Nomenclature System)
Basic UDI-DI : 899723944 NRPPLT AH and 899723944 NRPFLT 8X

We hereby declare that the medical device specified above meet the requirement of the Medical Device Regulation (EU) 2017/745, under Class I Medical Device set out in Rule number 5 of Annex VIII and PPE Regulation (EU) 2016/425. For the evaluation of the compliance with the Regulation, the following standards were applied:

Standard	Title	Edition/date
EN 455-1	Medical Gloves for single use: Requirements and testing for freedom from holes	2020
EN 455-2	Medical Gloves for single use: Requirements and testing for physical properties	2015
EN 455-3	Medical Gloves for single use: Requirements and testing for biological evaluation	2015
EN 455-4	Medical Gloves for single use: Requirements and testing for shelf life determination	2009
ISO 2859-1	Sampling procedures for inspection by attributes – Part 1: sampling plans indexed by acceptable quality level (AQL) for lot by lot inspection	1999
ASTM D-3578	Standard Specification for Rubber Examination Gloves for Medical Application	2019
EN ISO 374-1	Terminology and performance requirements for micro-organism risk	2016
EN 374-2	Determination of resistance to penetration	2014
BS EN 374-4	Determination of resistance to degradation by chemicals	2019
EN ISO 374-5	Terminology and performance requirements for micro-organism risk	2016
EN 16523	Determination of material resistance to permeation by chemicals	2015
EN ISO 21420	Protective gloves. General requirements and test methods	2020

Responsible for making this declaration is the:

(x) Manufacturer () Authorized representative established within the EU

Authorized Representative established within the EU :

Company name : **Obelis s.a.**
Address : Bd. Général Wahis 53, 1030 Brussels, Belgium
SRN : BE-AR-000000106

Person responsible for making this declaration

Name : Trixie
Position : Marketing Manager
Manufacturer's Name : **PT. LATEXINDO TOBAPERKASA**
 : Jl. Binjai Km. 11, Mulyorejo – Sunggal 20352, Deli Serdang ,
 : Sumatera Utara – Indonesia
 : (T) 62-61-8451410 ~ (F) 62-61-8451409
SRN : ID-MF-000009942

January 03, 2022



The image shows a handwritten signature in black ink over a purple rectangular stamp. The stamp contains the text "P.T. LATEXINDO TOBAPERKASA" on the top line and "MEDAN - INDONESIA" on the bottom line.

Trixie