EU Declaration of Conformity

According to Medical Device Regulation 2017/745

For the following Equipment,

Product : **Nitrile Examination Gloves Powder Free**
ECRI No. : 11882 (base on ECRI Universal Medical Device Nomenclature System)
Basic UDI-DI : 899720909 NBRPFUG DD

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. 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-6319	Standard Specification for Nitrile Examination Gloves for Medical Application	2019

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

This Declaration of Conformity is issued under the responsibility of:
Name : Trixie
Position : Marketing Manager
Manufacturer's Name : PT. UNIVERSAL GLOVES
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January 04, 2021

PT. UNIVERSAL GLOVES
SUMUT - INDONESIA

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Trixie