



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



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 and PPE Regulation (EU) 2016/425 carried out by SATRA (Notified Body 2777). 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
EN ISO 374-1	Terminology and performance requirements for chemical risk	2016
EN 374-2	Determination of resistance to penetration	2014
EN ISO 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 21420	Chemical innocuousness testing	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

This Declaration of Conformity is issued under the responsibility of:

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January 03, 2022



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