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)

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-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
BS EN 374-4	Determination of resistance to degradation by chemicals	2013
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 420	Protective gloves. General requirements and test methods	2003

Responsible for making this declaration is the:
(x) Manufacturer ( ) Authorized representative established within the EU

This Declaration of Conformity is issued under the responsibility of:

Name	: O. Kader
Position	: Group Commercial
Manufacturer's Name	: Snowdon & Bridge Ltd Unit 5, Crowland Business Park, Southport, PR9 7RS, United Kingdom

June 08, 2021

O. Kader