Declaration of Conformity

for the Self-Certification of Class 1 Medical Devices (Examination Gloves)

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Examination Gloves
Legal Manufacturer: (Name on Label)	[redacted]
Manufacturers SRN:	N/A (Not Yet Available)
Basic UDI-DI:	Powdered Latex Examination: 8859705100018CA Powder-Free Latex Examination: 8859705100025C7
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	For the covering of hands of medical staff during examination procedures involving patient body surfaces and patient body orifices.
MDR Classification:	Class I devices according to rules 5
Notified Body:	Not Applicable for Class I
EC Certificate:	Not Applicable for Class I
EU Authorised Representative:	CMC Medical Devices & Drugs S.L. Registered Place of business at C Horacio Lengo No18, CP 29006, Málaga, Spain.
EU Authorised Representative SRN:	ES-AR-000000293
Medical Device Regulation Assessment Route:	In conformity with Annex IV and Article 19 of the Medical Device Regulation; EU Declaration of Conformity

Name Miss Chalongkwan Wongsasuthikul **Position** Managing Director

Signed [redacted] **Date** 15/10/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN 455-1 : 2020	Part 1: Requirements and testing for freedom from holes
EN 455 -2 :2015	Part 2: Requirements and testing for physical properties
EN 455 -3 :2015	Part 3: Requirements and testing for biological evaluation
EN 455 -4 :2009	Part 4: Requirements and testing for shelf life determination
ISO 10993-1:2018	Part 1 : Evaluation and testing within a risk management process
ISO 10993-5:2009	Part 5 : Tests for *in* vitro cytotoxicity
ISO 10993-10:2010	Part 10 : Tests for irritation and skin sensitization
ISO 10993-12:2021	Part 12 : Sample preparation and reference materials.

Appendix II – Product Listing/Schedule

Catalogue Number	Device Name	Art. No.
S,M,L	Powdered Latex Examination Gloves	7865007 - 7865009
S,M,L,XL	Powder-Free Latex Examination Gloves	5315007 - 5315010

Version History

Version	Compiled by	Date	Description
1.0	[redacted]	01/05/2021	First issue
2.0	[redacted]	15/10/2021	2nd time