Declaration of Conformity

Manufacturer:
Name: DTS Trading Inc Ltd
Unit 1 Chiltern Vale Farm, Coopers Court Road, Stokenchurch, HP14 3UE, England.

EC Authorised Representative:
MedPath GmbH
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

UK Authorised Representative:
Name: MedPath Limited
27 Old Gloucester Street, London, United Kingdom, WC1N 3AX

Brand/Model: DTS Protect Vinyl Gloves (Clear, Blue)

Product Reference: 7321 Blue, 7322 (Clear)
Product: Vinyl Gloves, Powder Free
The materials and manufacturing process for all models of nitrile glove are identical. The products differ only in colour and thickness.

Sizes: Extra Small, Small, Medium, Large, X-Large, XXL

Risk Classification: Medical Device, Class I; PPE, Category III

We, DTS Trading Inc Ltd, herewith declare under our sole responsibility as the manufacturer that the above-mentioned products are in full compliance and conformity with the following Manufacturing Processes, European Regulations and Union Harmonized Standards

The product is in conformity with the following Manufacturing Processes:

Regulation number	Regulation name
EN ISO 9001:2015	The gloves are manufactured according to ISO 9001:2015 Quality Management Systems, as certified by CQC.
EN ISO 13485:2016	The gloves are manufactured according to ISO 13485:2016 Quality Management Systems. Specific for Medical Devices, as certified by Notified Body, TUV Rheinland.

The product is in conformity with the following UK and European Regulations:

Regulation number	Regulation name
Annex VIII of the Medical Device Regulation (EU) 2017/745	Regulation (EU) of the European Parliament and of the Council of 5. April 2017 on medical devices, with reference to the harmonized standard, EN455-l, EN455-2, EN455-3 and EN455-4 and is self-certified as a Class I non-sterile medical device.

European Medical Device Directive 93/42/EEC	Medical Devices Regulations 2002, UK Statutory Instruments 2002 No. 618, as amended, for Class I medical Devices.
Personal Protective Equipment (PPE)- Regulation (EU) 2016/425	Regulation (EU) of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment, Module C2 as a Category III product, and the requirement of the European harmonized standard EN ISO 21420:2020 & EN374 Parts 1/2/4/5. This has been certified by Notified Body CE 2777, SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Co.Meath, D15 YN2P, Republic of Ireland. This has also been certified by Approved Body 0321, SATRA Technology Centre Ltd, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, England.

The product is in conformity with the following Union Harmonized Standards:

Standard number	**Standard name**
EN ISO 21420:2020	Protective gloves - General requirements and test methods.
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009	Parts 1-4: Medical gloves for single use.
EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 374-4:2013, EN ISO 374-5:2016	Part 1: Protective gloves against dangerous chemicals, Type B, K/P/T. Part 2: Resistance to Penetration: Air & Water Part 4: Resistance to Degradation by Chemicals Part 5: Protective gloves against micro-organisms (Virus)
EN 1186:2002	Food Migration – Materials and articles in contact with food stuffs.
ISO 10993-5:2009	Biological evaluation of medical devices

Name: Henry Newman

CEO
DTS Trading Inc Ltd
Date: 01/07/2023