Declaration of Conformity

for Copolymer Examination Gloves

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

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:	Copolymer Examination Gloves
Legal Manufacturer:	No. 9, Zhangbin E. 2nd Rd., Xianxi Township, Changhua County 50741, Taiwan (R.O.C.)
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The device is intended for the covering of medical staff's hand during examination/nursing procedure on patient's skin.
MDD Classification:	Class I Sterile
Notified Body:	Notified Body 2460 DNV Product Assurance AS
CE Certificate Reference:	10146-2017-CE-RGC-NA-PS Rev 1.0
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	Production Quality Assurance outlined in Annex V

Name Peter C.F. Hsieh **Position** President

Signed **Date** 19 / 09 / 2023

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:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012 / ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing
N ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2018	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
EN ISO11137-1:2015	Sterilization of health care products — Radiation —Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO11137-2:2015	Sterilization of health care products. Radiation. Establishing the sterilization dose
EN ISO 11607-1:2019	Packaging for terminally sterilized medical devices -Part 1: Requirements for materials, sterile barrier system and packaging systems
EN 455-1:2020	Medical gloves for single use — Part 1: Requirements and testing for freedom from holes
EN 455-4:2009	Medical gloves for single use — Part 4: Requirements and testing for shelf life determination
EN 62366:2015	Medical devices - Application of usability engineering to medical devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
YN-66-SPS (S/M/L)	Ethylene vinyl acetate examination/treatment glove, non-powdered	59821
YN-66-DPS (S/M/L)	Ethylene vinyl acetate examination/treatment glove, non-powdered	59821
GS641 (S/M/L)	Clear Sterile Co-polymer Paper Backed Over-Gloves, Powder Free Brand: HandSafe UK Responsible Person: Polyco Healthline Ltd, South Fen Road, Bourne, Lincolnshire, PE10 0DN, United Kingdom	59821

Version History

Version	Compiled by	Date	Description
1.0	Juliee Hsieh	19 / 09 / 2023	First issue