EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:	Vincent Medical Manufacturing Co., Ltd. Flats B2, 7/F., Hang Fung Industrial Building, Phase 2, 2G Hok Yuen Street, Hung Hom, Kowloon, Hong Kong, China

It is hereby declared that the devices that listed in Product Range of this document conform with the provisions of the Meeica Device Direcctive 93/42/EEC as amended by directive 20007/47/EC of 21 Sepatember 2007 which apply.

Medical device:	Reusable HytrelTubing （VM pn 51051025）
of class:	IIa, rule 2 according to annex IX of directive 93/42/EEC
Conformity assessment procedure:	Directive 93/42/EEC Annex II, excluding Section 4
Registration No.:	HD60146949 0001
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Deutschland CE 0197
European Authorized Representative:	Obelis s.a Boulevard General Wahis, 53, 1030 Brussels, Belgium

Applicable Standards:

EN ISO 13485:2016	Medicl devices-Quality management system-Requirements for regulatory purpose
EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices-part 1:Evaluation and testing
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
BS EN 1041:2008+A1:2013	Information supplied by manufacturer of medical devices
ISO 5356-1:2015	Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets
ISO 5367:2014	Anaesthetic and respiratory equipment -- Breathing sets and connectors
ISO 14644-1: 2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
ASTM F1980	Standard Guide for Accelerated Aging of Sterile Barrier systems for Medical Devices
EN ISO 17665-1:2016	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 17664:2017	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

Eddy Kwok
Quality Assurance Manager

DongGuan, 2020-05-11

Place, date /

Name and function