Declaration of Conformity

Manufacturer :
Name: GA Health Company Limited
Address: Unit 18, 21/F, Metropole Square
2 On Yiu Street
Shatin, N.T.
HONG KONG

EC Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name	Product Code	UNDMS	Product Classification (MDD ANNEX IX)	Assessment Route
Disposable Polyp Trap	EN10103, EN10112, EN10113	13655	Rule I, Class I non-sterile	Annex VII

We here with declare that the above-mentioned products meet the provisions of the following council directive and harmonized standards for medical devices. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).
Standards applied: All Applicable harmonized European Standards (Refer to attachment 1)

Quality Management System Certification No.: Q6 104485 0001 Rev. 00
Date of Issue: 2019/11/26

Signature: _____ Date: 2019/12/03
Quality Assurance

Attachment 1 – Harmonized Standards for Medical Devices

No.	Name of Standards
1.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
2.	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
3.	EN ISO 14971:2007 Medical devices - Application of risk management to medical devices
4.	EN 1041:2008 Information supplied by the manufacturer of medical devices
5.	EN ISO 15223–1:2016 Medical devices- Symbols to be used with medical device labels, labeling and information to be supplied Part 1: General requirements
6.	EN ISO 11737-1:2006 Sterilization of medical devices -- Microbiological methods - Part 1: Determination of a population of microorganisms on products
7.	EN ISO 14644-1:2015 Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
8.	MEDDEV 2.4/1 classification of medical device
9.	MEDDEV 2.7/1 clinical evaluation a guide for manufacturers and notified bodies
10.	MEDDEV 2.12/1 Medical device vigilance system

Declaration of Conformity

Manufacturer :

Name: GA Health Company Limited

Address: Unit 18, 21/F, Metropole Square
2 On Yiu Street
Shatin, N.T.
HONG KONG

EC Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name	Product Code	UNDMS	Product Classification (MDD ANNEX IX)	Assessment Route
Air/Water Cleaning Valve	EN10920	17424	Rule I, Class I non-sterile	Annex VII

We here with declare that the above-mentioned products meet the provisions of the following council directive and harmonized standards for medical devices. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standards applied: All Applicable harmonized European Standards (Refer to attachment 1)

Quality Management System Certification No.: Q6 104485 0001 Rev. 00

Date of Issue: 2019/11/26

Signature: _____ Date: 2019/11/26

Quality Assurance

Attachment 1 – Harmonized Standards for Medical Devices

No.	Name of Standards
1.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
2.	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
3.	EN ISO 14971:2007 Medical devices - Application of risk management to medical devices
4.	EN 1041:2008 Information supplied by the manufacturer of medical devices
5.	EN ISO 15223–1:2016 Medical devices- Symbols to be used with medical device labels, labeling and information to be supplied Part 1: General requirements
6.	EN ISO 11737-1:2006 Sterilization of medical devices -- Microbiological methods - Part 1: Determination of a population of microorganisms on products
7.	EN ISO 14644-1:2015 Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
8.	MEDDEV 2.4/1 classification of medical device
9.	MEDDEV 2.7/1 clinical evaluation a guide for manufacturers and notified bodies
10.	MEDDEV 2.12/1 Medical device vigilance system