EU 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
SRN:	N/A

Authorized Representative:

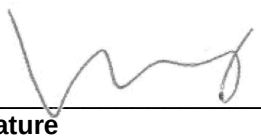
Name:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestrasse 80, 20537 Hamburg, Germany
SRN:	DE-AR-000000001

Product information:

Product Name	Product Code	Basic UDI-DI	CND	Risk Class and Rules
andorate® PearlCatch™ Single Chamber Polyp Trap	GAR014	489710695GAR014FD	G030899	Class I non-sterile, Rule 1
andorate® Four Chamber Polyp Trap	GAR023	489710695GAR023FE		
andorate® ThomasTrap™ Polyp Trap with Two Removable Chambers	GAR040	489710695GAR040FE		
andorate® Click4Catch™ Click into Place Polyp Trap with Four Removable Capture Chambers	GAR082	489710695GAR082FW		

This declaration of conformity is issued under the sole responsibility of GA Health Company Limited. We hereby declare that the aforementioned medical device(s) covered by the present declaration is in conformity with the Medical Device Regulation (EU) 2017/745 and applicable harmonized standards listed in Attachment 1 of this declaration. All supporting documentations are retained under the premises of the manufacturer.

Notified Body: N/A



Signature
Rainy Lam
Senior Regulatory Affairs Specialist

Hong Kong, 2021-04-30
Place, Date of Issue

Attachment 1 – Applicable Harmonized Standard

No.	Standard
1.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
2.	EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
3.	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
4.	EN 1041:2008/A1:2013 Information supplied by the manufacturer of medical devices
5.	EN ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process