



Template Version: 3.0

Version Number: 3.3

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## EU Declaration of Conformity (CE)


<b>Manufacturer</b>	GV Health Ltd.
<b>Manufacturer's Address</b>	Hall House, 2 Arlington Business Park, Stevenage, Hertfordshire, SG1 2FS, UK.
<b>Authorized Representative</b>	QbD RepS BV Groenenborgerlaan 16, 2610 Wilrijk, Belgium SRN: BE-AR-000000040
<b>Product Name</b>	PolyCare®
<b>Product Codes</b>	AOR4616, APW272, APB114, APY110, APG109, APP112, APR108, APW079, APG078, APG069, BTB000
<b>Basic UDI-DI</b>	5060215035AOR4616PG 5060215035APW272LJ, 5060215035APB114FC 5060215035APG109GN, 5060215035APP112JA, 5060215035APR108JZ, 5060215035APY110L5 5060215035APW079LN, 5060215035APG078H4, 5060215035APG069H3, 5060215035BTB000GM
<b>MD Category</b>	Class I, Non-sterile
<b>Justification</b>	Rule 1: "all non-invasive devices are Class 1, unless of the rules hereinafter applies" (Medical Device Regulation 2017/745, Annex VIII, Chapter 3).
<b>Product Description</b>	Healthcare Apron/Tabard
<b>GMDN Code</b>	32170
<b>GMDN Description</b>	A garment made of synthetic materials intended to be worn by healthcare providers, sometimes over scrub suits, while examining patients. It offers fluid resistance. An Apron/Tabard is used during patient examination procedures to protect both the patient and staff from the transfer of contaminants such as microorganisms or body fluids. This is a single-use garment.

It is declared that the above products:

*Device Classification:* Class I, Non-sterile medical device (Regulation (EU) 2017/745, MDR)

- are in conformity Medical Devices Regulation 2017/745 and verify that the Manufacturer has complied with self-certification in accordance with Annex IV of MDR and Annex II of PPE Regulation.
- Fulfils registration obligations under Articles 24 and 26.
- is in accordance with Regulation (EU) 2016/425 (PPE), meeting essential health and safety requirements in Annex II.
- are in conformity with the designated standards BS EN ISO 13485:2016.

This declaration of conformity is used under the sole responsibility of the manufacturer:

**Signed on behalf of:** GV Health Ltd.  
**Place of issue:** Stevenage, UK  
**Date:** 02 October 2025  
**Name and role:** Ike Nwagiriga, Regulatory Compliance Manager  
**Signature:** 

**Disclaimer:** This declaration and its accuracy are made, solely based on available information and data provided by our suppliers. This declaration will not discharge the user from his/her obligation to ensure the product is suitable for the intended use.



Certificate No. GB2004284 Certificate No. MD1348515 Certificate No. EM2001057