GV Health Limited
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GV Health
Life. Protected.

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EU Declaration of Conformity (CE)

Manufacturer	GV Health Ltd.
Manufacturer's Address	Hall House, 2 Arlington Business Park, Stevenage, Hertfordshire, SG1 2FS, UK.
Authorized Representative	QbD RepS BV Groenenborgerlaan 16, 2610 Wilrijk, Belgium SRN: BE-AR-000000040
Product Name	PolyCare®
Product Codes	AOR4616, APW272, APB114, APY110, APG109, APP112, APR108, APW079, APG078, APG069, BTB000
Pack sizes	PolyCare (200 pcs)- Roll // (1000pcs)- Case, PolyCare (200 pcs)- Roll // (1000pcs)- Case, PolyCare (200 pcs)- Roll // (1000pcs)- Case, PolyCare (200 pcs)- Roll // (1000pcs)- Case, PolyCare (200 pcs)- Roll // (1000pcs)- Case, PolyCare (200 pcs)- Roll // (1000pcs)- Case, PolyCare (200 pcs)- Roll // (1000pcs)- Case, PolyCare (75 pcs)- Roll // (450pcs)-Case, PolyCare (75 pcs)- Roll // (450pcs)- Case, PolyCare (25 pcs)- pcs per Flat Pack // (250pcs)-Case, Flat Pack Dispenser, PolyCare (250pcs)-Case, Box Dispenser
Basic UDI-DI	5060215035AOR4616PG 5060215035APW272LJ, 5060215035APB114FC 5060215035APG109GN,5060215035APP112JA, 5060215035APR108JZ,5060215035APY110L5 5060215035APW079LN,5060215035APG078H4, 5060215035APG069H3,5060215035BTB000GM
MD Category	Class I, Non-sterile
Justification	Rule 1: "*all non-invasive devices are Class 1, unless of the rules hereinafter applies*" (Medical Device Regulation 2017/745, Annex VIII, Chapter 3).
Product Description	Healthcare Apron/Tabard
GMDN Code	32170
GMDN Description	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.
EMDN Code	T0205
EMDN Description	Non-surgical gowns (excluding personal protective equipment - ppe)

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: 05 Feb 2026
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.

ISO 9001 Certificate No. GB2004284 | ISO 13485 Certificate No. MD1348515 | ISO 14001 Certificate No. EM2001057