

DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION (EU) 2017/745
PERSONAL PROTECTIVE EQUIPMENT REGULATION (EU)
2016/425

Legal Manufacturer

Gompels HealthCare Ltd
1 Swift Way
Bowerhill Ind. Est
Melksham
Wiltshire
SN12 6GX

Authorised representative in the EU

Gompels HealthCare Ltd

This certificate is valid for the following product:

Non-sterile examination and protective glove for single use

Classification: Class I according to MD Regulation (EU) 2017/745
Category I according to PPE Regulation (EU) 2016/425

UDI/GTIN: 88205 - 05060652761129
80311 - 05060652761099
17105 - 05060652761105
69547 - 05060652761112

Proform Vinyl Gloves Powder-Free 100 x 30

Sizes	X-Small	Small	Medium	Large	X-Large
Product codes	N/A	88205	80311	17105	69547

We hereby declare under sole responsibility that the CE marked product described above conforms to the requirements of the regulation for medical devices (EU) 2017/745.

Declaration based on Annex IV. Classification according rule 5, appendix VIII.

Applied standards: EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009

We hereby declare under sole responsibility that the CE marked product described above conforms with the applicable provisions of Regulation (EU) 2016/425 on personal protective equipment.

Applied standards: EN 420:2003+A1:2009

Sam Gompels
Director

This signed document is valid for all translations attached.

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