



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: 77774 - 05060160213790
84792 - 05060160213813
76776 - 05060160213837
78342 - 05060160213851
57814 - 05060160218504

Proform Latex Gloves Powder-Free 100 x 25

Sizes	X-Small	Small	Medium	Large	X-Large
Product codes	77774	84792	76776	78342	57814

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.

Issued : UK 25/02/2020 Expires: 25/02/2022

Released by: Sam Gompels