

EU Declaration of Conformity

We, **Regal Polythene Limited T/A Regal Disposables**, at Unit 2, Bennett's Lane, Widnes, Cheshire, WA8 0GW, hereby declare under our sole responsibility that the following Personal Protective Equipment (PPE) complies with:

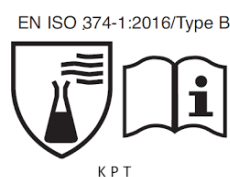
1. Model & Description *Safetouch Disposable Nitrile Gloves Powder Free*
(See Annex 1 for codes)
2. Glove Sizes S, M, L & XL
3. Manufacturer Regal Polythene Limited T/A Regal Disposables
Unit 2, Bennett's Lane
Widnes
Cheshire
WA8 0GW
4. Classification PPE - Category III-Complex
Medical Device Category – Class 1
5. Basic UDI-DI 506035275BNPF6J
6. It is in conformance with the regulation (EU) No 2016/425 of the European Parliament and of the council and national standards and, in some cases, in conformance with the harmonised standards conversion*.
7. It is in conformance with the provisions of UK MDR 2002 (SI 2002 No. 618, as amended) on Medical Devices and with designated standards EN 455-1:2020, EN 455-2:2015, EN455-3:2015 and EN 455-4:2009 and is self-certified as a Class 1 non-sterile medical device (according to Annex IX rule 5).

8. The notified body SATRA (Number: 2777) performed the EU type-examination, certificate number is 2777/12152-02/E02-01 (Module B) and assessment procedure Module C2 set out in Annex VII of Regulation (EU) 2016/425 as brought into UK law and amended, under surveillance issued by the notified body:

Notified Body number 2777
SATRA Technology Europe Limited
Bracetown Business Park
Clonee
County Meath
D15 YN2P
Ireland

9. The object of the declaration described in point 6* is in conformity with the relevant Union harmonization legislation: EN 420:2003+A1:2009, EN 16523-1:2015, EN 374-1:2016+A1:2018, EN 374-4:2013, EN ISO 374-5:2016.

10. Europe Standard: EN 374-2: 2014 EN ISO 374-1:2016+A1:2018
 EN 420:2003+A1: 2009 EN 16523-1:2015+A1:2018
 EN 374-4:2013 EN ISO 374-5:2016
 EN 455-1:2020 EN 455-2:2015
 EN 455-3:2015 EN 455-4:2009
 EN 1186-1:2002



For and on behalf of

Regal Polythene Limited T/A Regal Disposables

Daniel Crampton

Daniel Crampton

Date: 25.08.2021

Annex 1

Item	Product Code
White Nitrile Powder Free Gloves, Small	50000060
White Nitrile Powder Free Gloves, Medium	50000061
White Nitrile Powder Free Gloves, Large	50000062
White Nitrile Powder Free Gloves, Extra Large	50000063
Blue Nitrile Powder Free Gloves, Small	50000090
Blue Nitrile Powder Free Gloves, Medium	50000091
Blue Nitrile Powder Free Gloves, Large	50000092
Blue Nitrile Powder Free Gloves, Extra Large	50000093
Black Nitrile Powder Free Gloves, Small	50000251
Black Nitrile Powder Free Gloves, Medium	50000252
Black Nitrile Powder Free Gloves, Large	50000253
Black Nitrile Powder Free Gloves, Extra Large	50000254