

## 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 Vinyl Examination Gloves, Powdered  
*(see Annex 1 for codes)*  
Safetouch Disposable Vinyl Examination 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 I
- 5. Basic UDI-DI** Powdered - 506035275VLPGK  
Powder-Free - 506035275VPFGB
- 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 BSI (Number: 2797) performed the EU type-examination, certificate number is CE 716735 (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 to issue the EU type-examination certificate CE 630603, issued by the notified body:

Notified Body number 2797  
BSI Group The Netherlands B.V.  
Say Building, John M. Keynesplein 9, 1066 EP  
Amsterdam  
Netherlands

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 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016.

10. Europe Standard:
- |  |   |
|--|---|
| <input checked="" type="checkbox"/> EN 374-2: 2014       | <input checked="" type="checkbox"/> EN ISO 374-1:2016+A1:2018 |
| <input checked="" type="checkbox"/> EN 420:2003+A1: 2009 | <input checked="" type="checkbox"/> EN 16523-1:2015+A1:2018   |
| <input checked="" type="checkbox"/> EN 374-4:2013        | <input checked="" type="checkbox"/> EN ISO 374-5:2016         |
| <input checked="" type="checkbox"/> EN 455-1:2020        | <input checked="" type="checkbox"/> EN 455-2:2015             |
| <input checked="" type="checkbox"/> EN 455-3:2015        | <input checked="" type="checkbox"/> EN 455-4:2009             |
| <input checked="" type="checkbox"/> EN 1186-1:2002       |   |

EN ISO 374-1:2016/type C



EN374-5:2016



For and on behalf of

*Regal Polythene Limited T/A Regal Disposables*

*Daniel Crampton*

Daniel Crampton

Date: 15.10.2021

### Annex 1

Item	Product Code
Clear Vinyl Powdered Gloves, Small	50000001
Clear Vinyl Powdered Gloves, Medium	50000002
Clear Vinyl Powdered Gloves, Large	50000003
Clear Vinyl Powdered Gloves, Extra Large	50000004
Blue Vinyl Powdered Gloves, Small	50000020
Blue Vinyl Powdered Gloves, Medium	50000021
Blue Vinyl Powdered Gloves, Large	50000022
Blue Vinyl Powdered Gloves, Extra Large	50000023
Yellow Vinyl Powdered Gloves, Small	50000300
Yellow Vinyl Powdered Gloves, Medium	50000301
Yellow Vinyl Powdered Gloves, Large	50000302
Yellow Vinyl Powdered Gloves, Extra Large	50000303
Red Vinyl Powdered Gloves, Small	50000310
Red Vinyl Powdered Gloves, Medium	50000311
Red Vinyl Powdered Gloves, Large	50000312
Red Vinyl Powdered Gloves, Extra Large	50000313
Green Vinyl Powdered Gloves, Small	50000320
Green Vinyl Powdered Gloves, Medium	50000321
Green Vinyl Powdered Gloves, Large	50000322
Green Vinyl Powdered Gloves, Extra Large	50000323
Clear Vinyl Powder Free Gloves, Small	50000010
Clear Vinyl Powder Free Gloves, Medium	50000011
Clear Vinyl Powder Free Gloves, Large	50000012
Clear Vinyl Powder Free Gloves, Extra Large	50000013
Clear Vinyl Powder Free (Industrial) Gloves, Small	50000015
Clear Vinyl Powder Free (Industrial) Gloves, Medium	50000016
Clear Vinyl Powder Free (Industrial) Gloves, Large	50000017
Clear Vinyl Powder Free (Industrial) Gloves, Extra Large	50000018
Blue Vinyl Powder Free Gloves, Small	50000030
Blue Vinyl Powder Free Gloves, Medium	50000031
Blue Vinyl Powder Free Gloves, Large	50000032
Blue Vinyl Powder Free Gloves, Extra Large	50000033
Natural Synthetic Vinyl Powder Free Gloves, Small	50000200
Natural Synthetic Vinyl Powder Free Gloves, Medium	50000201
Natural Synthetic Vinyl Powder Free Gloves, Large	50000202
Natural Synthetic Vinyl Powder Free Gloves, Extra Large	50000203