

## 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:

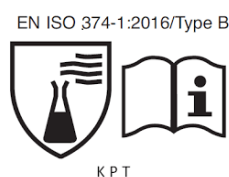
1. Model & Description *Safetouch Disposable Latex Gloves Powder Free/Powdered*  
*(See Annex 1 for codes)*
2. Glove Sizes S, M, L & XL
3. Manufacturer Regal Polythene Limited T/A Regal Disposables  
Unit 2, Bennett's Lane  
Widnes  
Cheshire  
WA8 0GW
4. Classification PPE - Category III-Complex  
Medical Device Category – Class 1
5. Basic UDI-DI Powdered - 506035275LLPEZ  
Powder-Free - 506035275LPFER
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, (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: 29.10.2021

**Annex 1**

<b>Item</b>	<b>Product Code</b>
Natural Latex Powdered Gloves, Small	50000040
Natural Latex Powdered Gloves, Medium	50000041
Natural Latex Powdered Gloves, Large	50000042
Natural Latex Powdered Gloves, Extra Large	50000043
Natural Latex Powder Free Gloves, Small	50000050
Natural Latex Powder Free Gloves, Medium	50000051
Natural Latex Powder Free Gloves, Large	50000052
Natural Latex Powder Free Gloves, Extra Large	50000053
Black Latex Powder Free Gloves, Small	50000055
Black Latex Powder Free Gloves, Medium	50000056
Black Latex Powder Free Gloves, Large	50000057
Black Latex Powder Free Gloves, Extra Large	50000058