

SKYTEC TX524

The manufacturer: Globus [Shetland] Ltd.  
T2 Trafford Park, Twining Road,  
Trafford Park, MANCHESTER, M17 1SH. United Kingdom.

Confirms conformity to: PPE Regulation (EU) 2016/425  
And the standard(s): ENISO21420:2020, EN374-1:2016+A1:2018 & EN374-5:2016

Of the following PPE product(s):  
SKYTEC TX524 – Five Fingered nitrile powder Free disposable Gloves

The Notified Body SATRA Technology, [NB No. 2777]  
performed the EU Type-Examination, [Module B], and issued the EU Type-Examination Certificate:  
2777/14815-03/E31-01

The PPE is subject to the conformity assessment procedure, conformity to type based on internal production control plus supervised product checks at random intervals, [Module D], under the surveillance of the Notified Body:  
SATRA Technology, [NB No. 2777]

Also

Medical Devices Directive 93/42/EEC as amended, Medical Devices Regulation (EU) 2017/745 as amended (effective from 26/05/2021), and with harmonised standards EN455-1:2000, EN455-2:2015, EN455-3:2015 and EN455-4:2009 and is Class I self-certified.

Signed for and on behalf of:  
Globus [Shetland] Ltd/, T2 Trafford Point, Twining Road,  
Trafford Park, MANCHESTER, M17 1SH. United Kingdom.



Name: Mr. Christian Halford  
Function: Regulatory & Quality Director

Date of issue: 12-Jan-23

EU Representative:  
Globus EMEA Ltd  
51 Dawson St  
Dublin  
D02 AN25 Ireland

D-o-C No.: SKYTEC TX524  
First Issued: 23/05/2022  
Issue No.: 03

UK/EU D-o-C (Internet Address): <https://gg-doc.com/Skytec>

## SKYTEC TX524

The manufacturer: Globus [Shetland] Ltd.  
T2 Trafford Park, Twining Road,  
Trafford Park, MANCHESTER, M17 1SH. United Kingdom.

Confirms conformity to: UK Regulation 2016/425 On PPE  
And the standard(s): ENISO21420:2020, EN374-1:2016+A1:2018 & EN374-5:2016

Of the following PPE product(s):  
SKYTEC TX524 – Five Fingerned nitrile powder Free disposable Gloves

The Approved Body SATRA Technology, [AB No. 0321]  
performed the EU Type-Examination, [Module B], and issued the EU Type-Examination Certificate:  
AB0321/19336-01/E04-01

The PPE is subject to the conformity assessment procedure, conformity to type based on internal production control plus supervised product checks at random intervals, [Module D], under the surveillance of the Approved Body:  
SATRA Technology, [AB No. 0321]

Also

Medical Devices Directive 93/42/EEC as amended, Medical Devices Regulation (EU) 2017/745 as amended (effective from 26/05/2021), and with harmonised standards EN455-1:2000, EN455-2:2015, EN455-3:2015 and EN455-4:2009 and is Class I self-certified.

Signed for and on behalf of:  
Globus [Shetland] Ltd/, T2 Trafford Point, Twining Road,  
Trafford Park, MANCHESTER, M17 1SH. United Kingdom.



Name: Mr. Christian Halford  
Function: Regulatory & Quality Director

Date of issue: 12-Jan-23

D-o-C No.: SKYTEC TX428  
First Issued: 23/05/2022  
Issue No.: 03

UK/EU D-o-C (Internet Address): <https://gg-doc.com/Skytec>