EU DECLARATION OF CONFORMITY

According to PPE Regulation (EU) 2016/425



SKYTEC TX510 - PROTECTIVE GLOVE

The manufacturer: Globus (Shetland) Ltd

T2 Trafford Point, Twining Road

Trafford Park, Manchester. M17 1SH. United Kingdom.

Confirms conformity to: PPE Regulation (EU) 2016/425 of the European Parliament and of the Council

And the standard(s): EN ISO 21420:2020, EN 374-1:2016+A1:2018 & EN 374-5:2016

Of the following PPE product(s):

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/E04-02

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.

And

Food Contact Regulation (EC) 1935/2004 & Regulation (EU) 10/2011

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: 16/01/2024