EU DECLARATION OF CONFORMITY

According to EU Regulation 2016/425 on PPE
& Regulation (EU) 2017/745 of 5th April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

SKYTEC
- UTAH

The manufacturer
Globus (Shetland) Ltd T2
Trafford Point Twining Road
Trafford Park Manchester
M17 1SH
UK

confirms conformity to: **EU Regulation 2016/425**
and standard(s): **EN420:2003+A1:2009, EN374-1:2016 & EN374-5:2016**

of the following PPE product:
SKYTEC UTAH

The Notified Body **SATRA Technology, [2777]**
performed the EU type-examination, (Module B), and issued the EU type-examination certificate: **2777/10919-03/E02-01**

The PPE is subject to the conformity assessment procedure, conformity to type based on quality assurance of the production process, (Module D), under the surveillance of the notified body:
SATRA Technology, [2777]

And

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, Twinin Road, Trafford Park,
Manchester, M17 1SH, UK

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

Date of Issue: **12-May-20**

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

AL-EU_DoC-0818

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Part of Globus GROUP