EU DECLARATION OF CONFORMITY

Haika NX510 & NX520

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):
HAIKA NX510 & NX520 – 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/E04-01

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 C2], 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-May-22

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

UK DECLARATION OF CONFORMITY

HAIKA NX510 & NX520

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):
HAIKA NX510 & NX520 – Five Fingered 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/E02-01

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 C2], 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.

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-May-22