

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): EN ISO21420:2020, EN 374-1:2016+A1:2018 & EN 374-5:2016

Of the following PPE product(s):
HAIKA NX510 & NX520 – Five Fingernitrile 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 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 EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009 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. Julien Magniez
Function: Regulatory & Quality Manager
Date of issue: 16-Jan-25

EU Representative:
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