

DECLARATION OF CONFORMITY

- Declaration as Medical Device, Class I -

The authorized European representative

*Top Glove Europe GmbH
Logport Office-Center
Bliersheimer Str. 80 A
D-47229 Duisburg
Deutschland*

declares on his sole responsibility that the following described products

<u>Item code</u>	<u>Description</u>	<u>Size</u>
13222-XS	Screen soft stretch Nitril blue	XS
13222-S	Screen soft stretch Nitril blue	S
13222-M	Screen soft stretch Nitril blue	M
13222-L	Screen soft stretch Nitril blue	L
13222-XL	Screen soft stretch Nitril blue	XL

Type: *Examination glove, non-sterile, powder-free, blue, class 1*
LOT-number: *See packaging*

manufactured by:

*TOP GLOVE SDN. BHD.
Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru,
41050 Klang,
Selangor D.E.,
MALAYSIA*

certified by:

<i>Standard:</i>	<i>ISO 9001:2015</i>	<i>Standard:</i>	<i>ISO 13485:2016</i>
<i>Issuer:</i>	<i>SIRIM QAS International Sdn. Bhd.</i>	<i>Issuer:</i>	<i>TÜV SÜD Management Service GmbH</i>
<i>Cert. No.:</i>	<i>QMS 03514</i>	<i>Cert. No.:</i>	<i>Q6 055729 0010 Rev. 03</i>
<i>Valid until:</i>	<i>30.04.2023</i>	<i>Valid until:</i>	<i>30.04.2023</i>

are in conformity with the essential requirements of the EU Directive 93/42/EEC, including its additions and amendmends by Directive 2007/47/EEC as well as the technical documentation and the conformity assessment procedure according to Annex VII. In accordance to the classification rule of EU Directive 93/42/EEC Annex IX the products are certified as medical device class 1.

Furthermore they comply with the following harmonized standards:

| EN 455-1:2000 | EN 455-2:2015 | EN 455-3:2015 | EN 455-4:2009 |

With regard to the use and utilization of the above mentioned product, we emphazise, that the instructions for use (see labelling on packaging) as well as the appropriate application and safety rules shall be followed in particular.

The user of the products bears the sole responsibility caused by improper usage or other than the intended use. In terms of the evidence of conformity all relevant documents are filed in our premises in accordance to current regulations and available for the authorities at any time.

Issuing date: *01.05.2020*
Expiry date: *30.04.2023*



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(Signature and company stamp)

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