The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
declares under his sole responsibility, that the PPE described hereafter:

## BioClean ${ }^{\text {™ }}$ <br> N-Plus BNPS Sterile Nitrile Cleanroom Gloves

Products manufactured till: [2027/12/19]
PPE to be used against category III risks

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 421:2010, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number $032 / 2022 / 1056$, issued by the Notified Body:

## CENTEXBEL (0493) <br> TECHNOLOGIEPARK 70 <br> B-9052 ZWIJNAARDE <br> BELGIUM

and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM


Guido Van Duren
Director - Regulatory affairs
Ansell

The Manufacturer
NITRITEX (M) SDN BHD,
NO.2, JALAN JURUNILAI U1/20,
SEKSYEN U1, HICOM GLENMARIE
INDUSTRIAL PARK,
40150 SHAH ALAM,
SELANGOR, MALAYSIA
declares under his sole responsibility, that the PPE described hereafter:

## BioClean N Plus BNPS sterile nitrile gloves

PPE to be used against category III risks
EN 421 EN ISO 374-5

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 421:2010, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex $V$ of the Regulation), under certificate number 060/2019/0068, issued by the Notified Body:

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CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM
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and is subject to the procedure set out in Annex VIII (Module D) of the Regulation under the supervision of the Notified Body:

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SGS FIMKO OY (0598)
TAKOMOTIE 8,
FI-00380 HELSINKI,
FINLAND
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Guido Van Duren
Director - Regulatory affairs
Ansell

