

EU DECLARATION OF CONFORMITY

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™ BIOTAC Nitrile Cleanroom Gloves

Products manufactured as of: [2024/08/26]

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 374-5:2016, EN ISO 374-1:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/1057, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
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

Place: Brussels
Date: 2024/08/26

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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™ BIOTAC Nitrile Cleanroom Gloves

Products manufactured as of: [2022/12/19] and till: [2024/08/25]

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 374-5:2016, EN ISO 374-1:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/1057, issued by the Notified Body:

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TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

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

SGS FIMKO OY (0598)
TAKOMOTIE 8,
FI-00380 HELSINKI,
FINLAND

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2022/12/19

EU DECLARATION OF CONFORMITY

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 Biotac BIOTAC Non-sterile Nitrile Gloves

Products manufactured till: [2022/12/18]

PPE to be used against category III risks

EN 421



EN ISO 374-1/Type C



EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 420:2003 + A1:2009, EN 421:2010, 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 060/2018/1871, issued by the Notified Body:

**CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM**

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

**SGS FIMKO OY (0598)
TAKOMOTIE 8,
FI-00380 HELSINKI,
FINLAND**

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2019/04/01