

欧盟符合性声明

制造商

ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

声明以下所述的个人防护设备由其全权负责:

BioClean™ Sterile Nitrile RABS/Isolator Mitten GGL30NITM9

适用产品起始日期 [2024/03/19]

用于防护category III风险的PPE

EN388: 2016



4102X

EN ISO 374-1:2016
Type A



AJKNOTS

EN ISO 374-5



VIRUS

EN 421



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 374-1:2016, EN ISO 374-5:2016, EN 421:2010 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0183, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

并须遵守该规例附件VI (模块D) 所载的程序:

Guido Van Duren
Director - Regulatory affairs
Ansell

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

地点: Brussels
日期: 2024/03/19

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制造商

ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

声明以下所述的个人防护设备由其全权负责:

BioClean™ Sterile Nitrile RABS/Isolator Mitten GGL30NITM9

适用产品起始日期 [2023/07/25] and till: [2024/03/18]

用于防护category III风险的PPE

EN388: 2016



4101X

EN 421



EN ISO 374-1:2016
Type A



AJKNOST

EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, 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 032/2023/0463, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

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Guido Van Duren
Director - Regulatory affairs
Ansell

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

地点: Brussels
日期: 2023/07/25

欧盟符合性声明

制造商

NITRITEK (M) SDN BHD,
NO.2, JALAN JURUNILAI U1/20,
SEKSYEN U1, HICOM GLENMARIE
INDUSTRIAL PARK,
40150 SHAH ALAM,
SELANGOR, MALAYSIA

授权代表:

NITRITEK LTD
UNIT 4, MINTON ENTERPRISE PARK
OAKS DRIVE, NEWMARKET
SUFFOLK, CB8 7YY, UK

声明以下所述的个人防护设备由其全权负责:

BioClean Sterile Nitrile mitten GGLxxNITM9

适用期至: [2023/07/24]

用于防护category III风险的PPE



3101

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, EN 388:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 060/2019/1028, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

并须遵守该规例附件VI (模块D) 所载的程序:



Guido Van Duren
Director - Regulatory affairs
Ansell

SGS FIMKO OY (0598)
TAKOMOTIE 8,
FI-00380 HELSINKI,
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地点: Brussels
日期: 2019/06/03