

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™ BIOTAC Nitrile Cleanroom Gloves

适用产品起始日期 [2024/08/26]

用于防护category III风险的PPE



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

并须遵守该规例附件VI (模块D) 所载的程序:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

地点: Brussels
日期: 2024/08/26

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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™ BIOTAC Nitrile Cleanroom Gloves

适用产品起始日期 [2022/12/19] and till: [2024/08/25]

用于防护category III风险的PPE



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

并须遵守该规例附件VI (模块D) 所载的程序:

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



Guido Van Duren
Director - Regulatory affairs
Ansell

地点: Brussels
日期: 2022/12/19

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

声明以下所述的个人防护设备由其全权负责:

BioClean Biotac BIOTAC Non-sterile Nitrile Gloves

适用期至: [2022/12/18]

用于防护category III风险的PPE



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

并须遵守该规例附件VI (模块D) 所载的程序:

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

地点: Brussels
日期: 2019/04/01