

# 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™ Prelude BPSL Sterile Latex Cleanroom Glove

适用产品起始日期 [2024/07/01]

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 374-1:2016, 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 032/2023/0014, 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: 2024/07/01

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BOULEVARD INTERNATIONAL 55  
B-1070 BRUSSELS  
BELGIUM

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## BioClean™ Prelude BPSL Sterile Latex Cleanroom Glove

适用产品起始日期 [2023/01/06] and till: [2024/06/30]

用于防护category III风险的PPE



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 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 032/2023/0014, issued by the Notified Body:

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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,  
FINLAND

地点: Brussels  
日期: 2023/01/06

## 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 Prelude BPSL Sterile Latex Gloves

适用期至： [2023/01/05]

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 060/2018/1775, issued by the Notified Body:

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

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Guido Van Duren  
Director - Regulatory affairs  
Ansell

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

地点： Brussels  
日期： 2019/04/01