

# 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-C™ Chemotherapy Protective Sleeve Covers (Sterile) S-BCSC**

*Products manufactured till: [2028/04/19]*

**PPE to be used against category III risks**

EN 13034:2005  
+ A1:2009



TYPE PB[6]

EN 14605:2005  
+ A1:2009



TYPE PB4

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 13034:2005 + A1:2009, EN 14605:2005 + A1:2009, EN ISO 13688:2013+A1:2021 and is identical to the PPE which is subject to the EU Type Examination; under certificate number 032/2023/0239 issued by the Notified Body:

**CENTXBEL (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**

A handwritten signature in blue ink, appearing to read 'Ulf Nystrom'.

**Ulf Nystrom**  
**Sr Manager, Regulatory Affairs PPE Products**

**Place: Malmö**  
**Date: 2023/04/19**

# EU DECLARATION OF CONFORMITY

The Manufacturer  
**NITRITEK (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-C Sleeve Covers - Sterile S-BCSC** **PPE to be used against category III risks**

EN 13034:2005  
+ A1:2009



TYPE PB[6]

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 13688:2013, EN 13034:2005 + A1:2009 and is identical to the PPE which is subject to the EU Type Examination; under certificate number 060/2019/0722 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**



**Ulf Nystrom**  
**Sr Manager, Regulatory Affairs PPE Products**

Place: Malmö  
Date: 2019/04/19