

# 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-D™ Sleeve Covers - Sterile S-BDSC-L**

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



PARTIAL BODY  
PROTECTION ONLY



TYPE PB [6]

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards Partial Body Protection Only, EN 1149-5:2018, EN ISO 13688:2013+A1:2021, EN 13034:2005 + A1:2009 and is identical to the PPE which is subject to the EU Type Examination; under certificate number 032/2023/0619 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: 2023/09/20**