

# 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 Coverall with Hood and Integrated Boots - Sterile S-BDFC**

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



**TYPE 5**



**TYPE 6**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 1149-5:2018, EN ISO 13688:2013, , EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009 and is identical to the PPE which is subject to the EU Type Examination; under certificate number 032/2023/0585 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: 2023-09-07**