

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