

# 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

PPE to be used against category III risks



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 14605:2005 + A1:2009, EN ISO 13688:2013+A1:2021, Partial Body Protection Only 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:

**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: 2023/04/19