

# 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**

EN 14605:2005  
+A1:2009



TYPE PB4



PARTIAL BODY  
PROTECTION ONLY

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**

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