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

Products manufactured till: [2028/04/19]

PPE to be used against category III risks



TYPE PB [6]

EN 14605:2005
+A1:2009



TYPE PB4

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 13034:2005 + A1:2009, EN 14605:2005 + A1:2009, EN ISO 13688:2013+A1:2021 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

EU DECLARATION OF CONFORMITY

The Manufacturer
NITRITEX (M) SDN BHD,
NO.2, JALAN JURUNILAI U1/20,
SEKSYEN U1, HICOM GLENMARIE
INDUSTRIAL PARK,
40150 SHAH ALAM,
SELANGOR, MALAYSIA

declares under his sole responsibility, that the PPE described hereafter:

BioClean-C Sleeve Covers - Sterile S-BCSC

PPE to be used against category III risks



TYPE PB [6]

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 13688:2013, EN 13034:2005 + A1:2009 and is identical to the PPE which is subject to the EU Type Examination; under certificate number 060/2019/0722 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: 2019/04/19