

EU DECLARATION OF CONFORMITY

The Manufacturer
NITRITEK (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-D Sleeve Covers - Sterile S-BDSC-L

PPE to be used against category III risks



EN 1149-5

EN 13034:2005
+ A1:2009



TYPE PB[6]

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 1149-5:2008, 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 060/2019/0738 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: 2019/04/25