

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:

HyFlex[®] 11-819 ESD

Products manufactured as of: [2024/10/01]

PPE to be used against category II risks

EN388: 2016



EN 16350



4121A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, EN 16350:2014 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0135.02, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VI (Module C) of the Regulation.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2024/10/01

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:

HyFlex[®] 11-819 ESD

Products manufactured as of: [2022/02/03] and till: [2024/09/30]

PPE to be used against category II risks

EN388: 2016



EN 16350



4121A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, EN 16350:2014 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0135, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VI (Module C) of the Regulation.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2022/02/03

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:

HyFlex® 11-819

Products manufactured till: [2022/02/02]

PPE to be used against category II risks

EN 388



4121A

EN 16350



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, EN 16350:2014, EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2020/1039, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VI (Module C) of the Regulation.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2020/07/31