

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® 11-925

Products manufactured as of: [2025/01/10]

PPE to be used against category III risks

EN388: 2016



411A

EN 407



X1XXXX



GR
ISO 18889

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020 , EN ISO 21420:2020, ISO 18889:2019 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0925.02, 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:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2025/01/10

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[®] 11-925

Products manufactured as of: [2022/10/25] and till: [2025/01/09]

PPE to be used against category III risks

EN388: 2016



4111A

EN 407



X1XXXX



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020 , EN ISO 21420:2020, ISO 18889:2019 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0925, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2022/10/25

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[®] 11-925

Products manufactured as of: [2021/12/14] and till: [2022/10/24]

PPE to be used against category III risks

EN388: 2016



411A

EN 407



X1XXXX



ISO 18889

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN407:2020, EN ISO 21420:2020, ISO 18889:2019 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2023/1386, issued by the Notified Body:

CENTEXBEL INTERNATIONAL LTD,
8 NORTHUMBERLAND AVENUE,
LONDON, WC2N 5BY,
UK

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2021/12/14

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[®] 11-925

Products manufactured as of: [2019/10/28] and till: [2021/12/13]

PPE to be used against category III risks



4111A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, EN 420:2003 + A1:2009, ISO 18889:2019 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/1589, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2019/10/28

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[®] 11-925

Products manufactured till: [2019/10/27]

PPE to be used against category II risks



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is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2003, EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EC Type examination; under certificate number 032/2015/0640 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: 2015/06/02