

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® 11-561

Products manufactured as of: [2024/12/05]

PPE to be used against category II risks

EN388: 2016



4X42C

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 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2024/0705, 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: 2024/12/05

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[®] 11-561

Products manufactured as of: [2024/07/22] and till: [2024/12/04]

PPE to be used against category II risks

EN388: 2016



4X42C

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0065, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
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BELGIUM

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

A handwritten signature in black ink, appearing to read 'Guido Van Duren', written over a horizontal line.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2024/07/22

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® 11-561

Products manufactured as of: [2022/01/25] and till: [2024/07/21]

PPE to be used against category II risks

EN388: 2016



4X42C

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0065, issued by the Notified Body:

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

A handwritten signature in black ink, appearing to read 'Guido Van Duren', written over a horizontal line.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2022/01/25

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® 11-561

Products manufactured till: [2022/01/24]

PPE to be used against category II risks



4X42C

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 420:2003 + A1:2009, EN 388:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2019/1428, 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: 2019/09/20