

EU DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

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

HyFlex™ 11-543

Products manufactured as of: [2026/06/04]

PPE to be used against category II risks

EN 16350



EN388: 2016



EN 407



4X32F

X1XXXX

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 16350:2014, 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 032/2026/0311, 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: 2026/06/04

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The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

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

HyFlex® 11-543

Products manufactured as of: [2024/06/25] and till: [2026/06/03]

PPE to be used against category II risks

EN388: 2016



4X32F

EN 407



X1XXXX

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, EN407:2020 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2023/0550.02, 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: 2024/06/25

EU DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

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

HyFlex® 11-543

Products manufactured till: [2024/06/24]

PPE to be used against category III risks

EN388: 2016



4X32F

EN 407



X1XXXX

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016 +A1:2018, EN ISO 21420:2020, EN407:2020 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2023/0550, 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: 2023/08/28