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

and authorized representative:
PATIENT GUARD LTD
LANCASTER HOUSE,
AMY JOHNSON WAY,
BLACKPOOL, LANCASHIRE,
FY4 2RP, UNITED KINGDOM
INFO@PATIENTGUARD.CO.UK

declare under their sole responsibility, that the PPE described hereafter:

HyFlex® 11-840

Products manufactured as of: [2024/09/01]

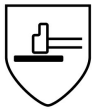
PPE to be used against category II risks

EN 407



X1XXXX

EN388: 2016



4131A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN407:2020 , EN ISO 21420:2020, EN 388:2016 +A1:2018 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0622.02, 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: 2024/09/01

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® 11-840

Products manufactured as of: [2022/06/03] and till: [2024/08/31]

PPE to be used against category III risks

EN 407



X1XXXX

EN388: 2016



4131A

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN407:2020 , EN ISO 21420:2020, EN 388:2016 +A1:2018 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0622, 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: 2022/03/06

EU DECLARATION OF CONFORMITY

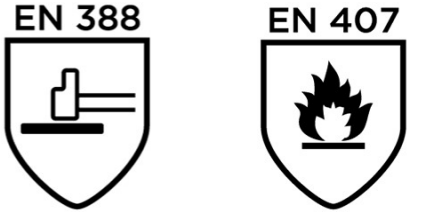
The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM
WWW.ANSELL.COM

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

HyFlex® 11-840

Products manufactured as of: [2020/12/21] and till: [2022/06/02]

PPE to be used against category III risks



4131A X1XXXX

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 388:2016, EN 420:2003 + A1:2009, EN 407:2004 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2020/1533, 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: 2020/12/21

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® 11-840

Products manufactured till: [2020/12/20]

PPE to be used against category II risks

EN 388



4231

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 03213141 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: 2013/01/29