

# UK 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

UK Importer  
**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:

## Edge® 48-216

*Products manufactured as of: [2025/01/29]*

PPE to be used against category III risks

EN388: 2016



4133B

EN 407



413X4X

is in conformity with the provisions of Regulation 2016/425 on personal protective equipment, as amended to apply in GB, and with the standards EN 12477:2001 + A1:2005, EN 388:2016 +A1:2018, EN ISO 21420:2020, EN407:2020 and is identical to the PPE which is subject to the UK Type-examination (Module B, Annex V of the Regulation), under certificate number 032/2021/1104.02, issued by the Approved Body:

**CENTEXBEL (0493)**  
TECHNOLOGIEPARK 70  
B-9052 ZWIJNAARDE  
BELGIUM

and is subject to the conformity assessment procedure set in out in Annex VIII (Module D) of the Regulation under the surveillance of the Body:

**CENTEXBEL (0493)**  
TECHNOLOGIEPARK 70  
B-9052 ZWIJNAARDE  
BELGIUM



Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2025/01/29

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BOULEVARD INTERNATIONAL 55  
B-1070 BRUSSELS  
BELGIUM  
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declares under his sole responsibility, that the PPE described hereafter:

**Edge® 48-216**

*Applicable Until [2025/01/28]*

**PPE to be used against category III risks**

EN388: 2016



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is in conformity with the provisions of Regulation 2016/425 on personal protective equipment, as amended to apply in GB, and with the standards EN 12477:2001 + A1:2005, EN 388:2016 +A1:2018, EN ISO 21420:2020, EN407:2020 and is identical to the PPE which is subject to the UK Type-examination (Module B, Annex V of the Regulation), under certificate number AB0321/24150-01/E00-00, issued by the Approved Body:

**SATRA TECHNOLOGY CENTRE (0321)**  
WYNDHAM WAY, TELFORD WAY,  
KETTERING, NORTHAMPTONSHIRE,  
NN16 8SD, UNITED KINGDOM

and is subject to the conformity assessment procedure set out in Annex VII (Module C2) of the Regulation under the surveillance of the Approved Body:

**SATRA TECHNOLOGY CENTRE (0321)**  
WYNDHAM WAY, TELFORD WAY,  
KETTERING, NORTHAMPTONSHIRE,  
NN16 8SD, UNITED KINGDOM

Guido Van Duren  
Director – Regulatory affairs  
Ansell

Place: Brussels  
Date: 2023/05/09