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:

GAMMEX® Latex Long Cuff

Products manufactured as of: [2024/11/20]

PPE to be used against category III risks







is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 421:2010, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0434.02, 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: 2024/11/20

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

GAMMEX® Latex Long Cuff

Products manufactured till: [2024/11/19]

PPE to be used against category III risks







is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 421:2010, EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2022/0434, issued by the Notified Body:

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Guido Van Duren

Director - Regulatory affairs

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Place: Brussels Date: 2022/03/18