

# UK DECLARATION OF CONFORMITY

The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
RIVERSIDE BUSINESS PARK, BLOCK J  
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UK Importer  
**UK IMPORTER**  
ANSELL (U.K.) LIMITED  
BUILDING C, WILLERBY HILL  
BUSINESS PARK  
WILLERBY, HULL  
UNITED KINGDOM, HU10 6FE

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

## AlphaTec® 58-001

PPE to be used against category III risks

EN 16350



EN388: 2016



EN ISO 374-1:2016  
Type A



AJKLOPT

EN ISO 374-5



VIRUS

4101X

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 16350:2014, EN 388:2016 +A1:2018, 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 UK Type-examination (Module B, Annex V of the Regulation), under certificate number AB0321/22862-01/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 in out in Annex VIII (Module D) 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: 2022/11/16