

**Ansell Healthcare Europe N.V.**

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Boulevard International 55

Block J  
B-1070 Brussels

Tel. 32 (0)2-528 74 00  
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## EC DECLARATION OF PRODUCT CONFORMITY

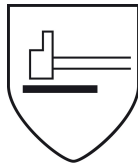
### Category III

The manufacturer, established in the European Economic Community:

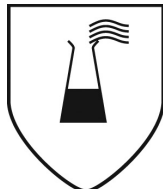
**ANSELL HEALTHCARE EUROPE N.V.  
RIVERSIDE BUSINESS PARK, BLOCK J  
BOULEVARD INTERNATIONAL 55  
B-1070 BRUSSELS**

declares that the PPE described hereafter:

### AlphaTec® 58-535B



EN 388: 2003  
4121



JKL



X1XXXX



is in conformity with the provisions of the Council Directive 89/686/EEC and with the European harmonised standards EN420:2003+A1:2009, EN388: 2003, EN374: 2003, EN407: 2004, and is identical to the PPE which is subject to the EC Type Examination certificate number 3205494 issued by the Notified Body:

**CENTEXBEL (0493)  
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B-9052 ZWIJNAARDE**

is subject to the procedure set out in Article 11 point A of Directive 89/686/EEC under the supervision of the Notified Body

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Friday, 09 March 2018  
Guido Van Duren  
Director – Global Regulatory Affairs  
PPE Products  
Ansell