

# EU DECLARATION OF CONFORMITY

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

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

**AlphaTec<sup>®</sup> 1800 COMFORT BC - Model 193**  
**PPE to be used against category III risks**



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards , EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009, EN ISO 13688:2013 and is identical to the PPE which is subject to the EU Type Examination; under certificate number 0598/PPE/21/2733 issued by the Notified Body:

**SGS FIMKO OY (0598)**  
**TAKOMOTIE 8,**  
**FI-00380 HELSINKI,**  
**FINLAND**

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

**SGS FIMKO OY (0598)**  
**TAKOMOTIE 8,**  
**FI-00380 HELSINKI,**  
**FINLAND**



**Ulf Nystrom**  
**Sr Manager, Regulatory Affairs PPE Products**

**Place: Malmö**  
**Date: 2024/09/05**