

# 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® 4000 Ultrasonically Welded & Taped - Model 122**

**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 13688:2013, EN 14605:2005 + A1:2009, EN ISO 13982-1:2004 + A1:2010, EN 1073-2:2002, EN 14126:2003, EN 1149-5:2018 (with exception for resistance to ignition not tested) and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 0598/PPE/22/4393, 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: 2024/09/19**