

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 125-G05

PPE to be used against category III risks



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards , EN 14605:2005 + A1:2009, EN ISO 13982-1:2004 + A1:2010, EN 1073-2:2002, EN 1149-5:2018, EN 14126:2003, EN ISO 13688:2013 (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