



DECLARATION OF CONFORMITY WITH EUROPEAN UNION REGULATION

Manufacturer:

OPRO International Limited
24 Mark Road
Hemel Hempstead
Hertfordshire
HP2 7BN
United Kingdom

We the undersigned certify and declare under our sole responsibility that the following apparatus

DoC Reference No.:

D-Custom-Fit-002

Conforming Apparatus:

Custom-Fit Mouthguard, all models and colours

EU type examination certification (Module B) issued by:

SATRA Technology Europe Limited, European Notified
Body Number 2777
EU type examination certificate number 2777/11625-
02/E00-00

Technical File Reference No.:

05 R 01

Technical File Document Names:

Personal Protective Equipment - Mouthguards

**Harmonised Standards Applied or
Referenced and Other Standards:**

SATRA M33:2022

Authorized Representative:

Eurolink Europe Compliance Limited
25 Herbert Place
Dublin D02 AY86
Republic of Ireland

conforms to the requirements of PPE Regulation 2016/425 relating to personal protective
equipment

Signed:

Dr Anthony Lovat
Managing Director
OPRO International Limited

Place: Dublin, Republic of Ireland**Date:** 2 January 2024