



## 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-Instant Custom-Fit-002

**Conforming Apparatus:**

Instant 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 2777/10654-  
04/E00-00

**Technical File Reference No.:**

14 R 00

**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