

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC Signatory of EA, IAF and ILAC Mutual Recognition Agreements





## **EU Type Examination Certificate**

Date: 2024/06/14 n. **1069242403/OE** Validity: 2029/06/13

The hereunder described items of Personal Protective Equipment have overcome positively the "EU type examination" (Module B), proving their conformity to the safety and health requirements of the Regulation (EU) 2016/425 (Annex II)

Manufacturer: (Responsible of the PPE)	PROTECTIVE SPORTSWEAR LTD. Unit 10 Birch Lane Business Park, WS9 0NF Aldridge – UK	
Type of PPE:	MOUTHGUARDS	
Category of PPE:	II: "medium" risks.  This certificate is based on reference standards listed below: its validity is no longer ensured should new version of the standards come into force.	
Model	"ORTHO SERIES"	

Description: <u>Product description</u>:

2-layer orthodontic mouthguard providing protection to top teeth and braces as well as the lips, whilst also including a front addition that prevents lower lip soft tissue damage. The mouthguard is mouldable with a brace channel for comfort;

Colourways:

6 (Red, Black, Clear/Pink, Clear/Blue, Black/White, Clear).

Red	Black	Clear/Pink	
Clear/Blue	Black/White	Clear	

Technical Standard:	Ricotest Internal Method M <mark>e-</mark> Int 121-00	Mouthguards - Specific protocol to determine the material innocuousness as well as the impact resistance
Intended use:	preventive use against impacts that can occur when practicing contact and semi- contact sports	
Size range:	One size fits all	
Technical File:	DC-17808	
Test report:	RCT n° 4214626/EC	





## DBD No USSU B

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Functions and performance levels:

to reduce the severity of injuries caused by impacts.

Method: Flat impactor (2,5 Kg) - Values achieved at an impact energy of 2J and 5J

Requirement: ≤ 10 kN = PASS

Marking:

Printed on the packaging and displaying the following information:

CE Marking;

- name, address and trademark of the Manufacturer and the Manufacturer's authorised representative;
- item designation (article name);
- pictogram "i in a book" instructing to read the User's Instructions;
- size indication;
- batch number and "Made in...".









Protective Sportswear Ltd.
Unit 10 Birch Lane Business Park, WS9 ONF, UK
Authorised EU Representative: Gahman (Europe) Ltd.
Unit 3D North Point House, T23 AT2P, Ireland

BATCH NO#: 0421-1 © All rights reserved. Made in China.



NOTE: the Technical File contains a more detailed description of the PPE (material, method of assembly, photographs or drawings), performance data, safety functions and level of protection, elements of conformity to the basic and supplementary requirements.

The Technical File is integral part of the present Certification, which has to be kept available by the applicant to be forwarded - upon request - to the entitled person (supervising body, Controlling Officer).



