

EU Type Examination Certificate

Date: 2021/05/19

n. **918212001/OE**

Validity: 2026/05/18

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)	ERKODENT ERICH KOPP GmbH Siemensstraße 3, 72285 Pfalzgrafenweiler, GERMANY
Type of PPE:	Mouthguard
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	"PLAYSAFE TRIPLE" (*)
Description:	Thermoformed mouth-guard fabricated out of three foils with hard mid-layer, declared EVA-COC-EVA and available in 15 colour variants: 1- bright red, 2- bright yellow, 3- bright blue, 4- bright green, 5- bright pink, 6- light blue, 7- transparent, 8- deep red, 9- dark blue, 10- maroon, 11- deep green, 12- pure white, 13- deep black, 14- gold, 15- silver. 10 further freestyle models are also available: 16- camouflage, 17- lava, 18- tie-dye, 19- rainbow, 20- confetti, 21- zebra, 22- gold flakes, 23- silver flakes, 24- camouflage strip, 25- lava strip. The mouth-guards can also be customized as per the user's requests: they can be composed with up to four colours out of the colours 1 to 15. (*) These items are also available in a version especially suited in case of cramped oral situation.: PLAYSAFE TRIPLE LIGHT .
Technical Standard:	Ricotest Internal Method Specific protocol to determine the material innocuousness as well as the impact energy absorption
Intended use:	Protection of the teeth against impacts that can occur when practicing sport activities.
Size range:	Made to measure
Technical File:	DC-11593
Test report:	RCT n°3930924/E

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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

Marking:

printed either on the protector or on the packaging and displaying the following information:

- **CE Marking;**
- name of the Manufacturer;
- item designation;
- batch nr. and date of manufacture (year/month);
- pictogram instructing to read the User Manual.



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).

