


# EU Declaration of Conformity

## for Lip Bumper

<b>Legal Manufacturer: (Name on Label)</b>	Oriental International Supplies Ltd
<b>EU Authorised Representative:</b>	SHARE INFO GMBH/ Am Schulzentrum 12, 41564 Kaarst, Germany
<b>Statement:</b>	This EU declaration of conformity is issued under the sole responsibility of Oriental International Supplies Ltd.
<b>PPE Product name:</b>	Lip Bumper/Lip Protector
<b>PPE Product code:</b>	LP-001; LP-002
<b>Intended Purpose:</b>	To cover the orthodontic brackets, to reduce discomfort and abrasion of soft tissue inside the oral cavity
<b>Risk Class:</b>	Class I
<b>Regulation:</b>	The device covered by this declaration is covered by Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 <sup>th</sup> March 2016 concerning personal protective equipment. The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.
<b>Applicable standards and common specifications:</b>	As per Appendix I (of this document) – Applicable Standards
<b>Notified Body:</b>	Not applicable, class I product
<b>Conformity Assessment Procedure:</b>	In conformity with Annex IV – Module A Internal Production Control of the EU Personal Protective Equipment Regulation
<b>EC Certificate:</b>	Not applicable, class I product

<b>Place:</b>	China	<b>Date of Issue:</b>	22/04/2025
<b>Signature:</b>			
<b>Name:</b>	Carla Yao	<b>Function:</b>	Sales Manager

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the product is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

### Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2016/425	Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016 concerning personal protective equipment