



# Technical File for CE declaration letters – Spectacle frames

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Collection Name	COMPACTO	Model No.	452925701
Product Name	Spectacle frames	Ref. Standards	ISO 12870:2016
A. Product Photo / Tech. Specs.	Attach photo / drawing		
	Front:		
			
	Side:		
			
	Weight: 13g	Size: 53□16mm	Inclination: 9°
	lens type: / e.g. /	Temple length: 140mm	Front Curve: 4.5
B. Material List	Laboratory test result refers to the attached test reports		
Parts Name	Code #	Supplier	Material
Eye rims	PEI1000-1000	RUNCHI	Ultem
Bridge	PEI1000-1000	RUNCHI	Ultem
Temples	PEI1000-1000	RUNCHI	Ultem
Trim/end-piece	/	/	/
Nosepads	/	/	/
Hinge/Flex	XB3075-17	GAOHUA	Cupronickel
Rimlock	/	/	/
Color 1 s.crystal teal	Front material Ultem	Temple / tip material Ultem	Color Paint / Plating description S.black
	Lens material /	Lens color description /	Lens coating ( ) UV blocking ( ) AR coated ( ) hard coating ( ) polarize ( )
Color 2 /	Front material /	Temple / tip material /	Color Paint / Plating description /
	Lens material /	Lens color description /	Lens coating ( ) UV blocking ( ) AR coated ( ) hard coating ( ) polarize ( )
Color 3 /	Front material /	Temple / tip material /	Color Paint / Plating description /
	Lens material /	Lens color description /	Lens coating ( ) UV blocking ( ) AR coated ( ) hard coating ( ) polarize ( )
Remarks			

## Templates of CE declaration letters – Spectacle frames

Issue by (Manufacturer / Exporter): Wenzhou Hivision Eyewear Co.,Ltd.

Full Address in English: No.1 Building, No. 55 Xinyi Road, Wenzhou, Zhejiang, China

Country of origin: China

### **DECLARATION OF CE CONFORMITY: European Directive 2007/47/EC concerning medical devices (Spectacle frames)**

We hereby declare that the following products, in view of the design, construction and material, comply with the essential requirements of the captioned EC Directive. The undersigned is the quality representative of our company to declares that the Spectacle frames we designs, manufacturers and supplies are in conformity with the provisions for medical devices in Directive 2007/47/EC and meet the requirements set forth in **ISO 12870:2016**.

Collection Name: COMPACTO

Model Numbers and its variants:

452925701

Relevant Directive: Medical Device Directive 2007/47/EC

Related test standards: ISO 12870:2016 Spectacle frames with demo lenses  
EN16128 Nickel Release on coated sunglasses

Importer/Distributor in Europe:

This is the result of test that was carried out from the submitted type-sample of a product in conformity with specification of the respective standards. The certificate holder has the right to affix the CE mark on the product complying with the inspection sample.

Wenzhou April 10,2019

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Place and date of issue

温州海诚眼镜有限公司  
WENZHOU HIVISION EYEWEAR CO.,LTD

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Name & signature of authorized staff (with company stamp)