

DECLARACIÓN UE DE CONFORMIDAD / EU DECLARATION OF CONFORMITY REGLAMENTO (UE) 2017/745 DEL PARLAMENTO Y DE LA COMISIÓN DE LA UNIÓN EUROPEA del 5 de abril de 2017 sobre los PRODUCTOS SANITARIOS <i>REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on MEDICAL DEVICES</i>		
FABRICANTE (Nombre / marca o nombre comercial del fabricante dirección completa legal) MANUFACTURER (Name / Brand or commercial name of the manufacturer/complete legal address)	Superb Vision International Trading (Hangzhou) Co.,Ltd. Room 301,building 7,xixi century center,No.136 Shuanglong street,Xihu district, Hangzhou,Zhejiang,China.	
SRN (FABRICANTE/MANUFACTURER)	CN-MF-000024745	
REPRESENTANTE AUTORIZADO EN EUROPA/ AUTHORIZED EUROPEAN REPRESENTATIVE:	SUPERBVISION OPTIK S.L. Rúa Oliveira 27, 36163 Poio, Pontevedra (España).	
AUTORIDAD COMPETENTE/COMPETEN AUTHORITY	Agencia Española del Medicamento y Productos Sanitarios C/ Campezo, 1 28022 Madrid psinstal@aemps.es	
SRN (REPRESENTANTE AUTORIZADO EN EUROPA/ AUTHORIZED EUROPEAN REPRESENTATIVE	ES-AR-000017930	
DECLARA BAJO SU PROPIA RESPONSABILIDAD COMO FABRICANTE QUE LOS PRODUCTOS QUE SE DESCRIBEN A CONTINUACIÓN SON CONFORMES AL: REGLAMENTO (UE) 2017/745 DEL PARLAMENTO Y DE LA COMISIÓN DE LA UNIÓN EUROPEA DEL 5 DE ABRIL DE 2017 SOBRE LOS PRODUCTOS SANITARIOS <i>DECLARE UNDER THEIR RESPONSIBILITY AS MANUFACTURER THAT THE PRODUCTS DESCRIBES BELOW MEET THE REQUIREMENTS OF THE REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES</i>		
DESCRIPCIÓN DEL PRODUCTO / PRODUCT DESCRIPTION DESCRIPCIÓN DEL PRODUCTO / PRODUCT DESCRIPTION MONTURAS PARA LENTES GRADUADAS/ CORRECTIVE: SPECTACLE FRAMES REFERENCIA /ARTICLE CODE: JB 001A,JB 002M,JB 003C,JB 004M,JB 007C,JB 008M,JB 009C,JB 010M,JB 013C,JB 014C,JB 015C,JB 016M,JB 017C,JB 018C,JB 005M, JB 006M,JB 011C,JB 012C,JB 020A,JB 024C,JB 026C,JB 027C,JB 028C,JB 030M,JB 031M,JB 032M,JB 019A,JB 023C,JB 025M,JB 029C, JB 033C,JB 034C,JB 021C,JB 022C,JB 035C,JB 036C,JB 037C,JB 038M,JB 039M,JB 040M,JB 041M,JB 042C,JB 043C,JB 044C,JB 045C, JB 046C,JB 047M,JB 048M,JB 049M,JB 050C,JB 051C,JB 052C,JB 053A,JB 054A,JB 055M,JB 056C,JB 057M,JB 058A,JB 059A,JB 060M, JB 061C,JB 062C,JB 063M,JB 064C,JB 065M,JB 066C,JB 067M,JB 068C,JB 069C,JB 070C,JB 071C,JB 072C,JB 073A,JB 074A,JB 078A, JB 079A,JB 084A,JB 075C,JB 076M,JB 077M,JB 080C,JB 081M,JB 082A,JB 083C,JB 085A,JB 086A,JB 087A,JB 088C,JB 089A,JB 090A, JB 091C,JB 092M,JB 093M,JB 094C,JB 095M,JB 096M,JB 097A,JB 098A,JB 099A,JB 100A,JB 101C,JB 102M,JB 103C,JB 104C,JB 105A, JB 106A,JB 107A,JB 108A,JB 109M,JB 110M,JB 111C,JB 112C,JB 113M,JB 114C,JB 115C,JB 116C,JB 117C,JB 118M,JB 119A,JB 120A, JB 121A,JB 122M,JB 123A,JB 124A,JB 125C,JB 126M,JB 127C,JB 128C,JB 129M,JB 130A,JB 131A,JB 132C,JB 133C,JB 134M,JB 135A, JB 136A,JB 137A,JB 138A,JB 139M,JB 140M,JB 141C,JB 142C,JB 143M,JB 144M,JB 145M,JB 146M,JB 147C,JB 148C,JB 149A,JB 150A, JB 151C,JB 152A,JB 153A,JB 154A,JB 155A,JB 156A,JB 157A,JB 158C,JB 159M,JB 160M,JB 161M,JB 162C,JB 163C,JB 164A,JB 165M, JB 166A,JB 167A,JB 168C,JB 169A,JB 170A,JB 171C,JB 172M,JB 173C,JB 174M,JB 175A,JB 176C,JB 177M,JB 800C,JB 801A KC1000A,KC1001A,KC1002A,KC1003C,KC1004M,KC1005A,KC1006A,KC1007A,KC2000A,KC2001A,KC2002A,KC2003C,KC2005A,KC2006A, KC3000A,KC3001A,KC3003A,KK1036,KK1037,KK1038,KK1039,KK1040,KK1041,KK1042,KK1045,KK1046,KK1047,KK1048,KK1049,KK1050, KK1051,KK1052,KK1053,KK1054,KK1055,KK1056,KK1057,KK1058,KK1059,KK1060,KK1061,KK1062,KK1063,KK1064,KK1065,KK1066,		

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FINALIDAD PREVISTA / INTENDED USE:

Dispositivo oftálmico hecho de metal, acetato o plástico para incluir lentes ópticas fabricadas de acuerdo con una prescripción estándar y que se utilizan para corregir los errores de refracción de la vista de un paciente, por ejemplo, la ametropía refractiva (miopía, hipermetropía y astigmatismo), y posiblemente para proteger los ojos contra la radiación o los riesgos mecánicos.

An ophthalmic device made of metal, acetate, or plastic in order to include optical lenses manufactured in accordance with a standard prescription and used to correct the refractive errors of a patient's eyesight, e.g., refractive ametropia (myopia, hyperopia, and astigmatism), and possibly to protect the eyes against radiation or mechanical hazards.

UDI-DI BÁSICO / UDI-DI BASIC:

Superb Vision International Trading (Hangzhou) Co., Ltd.

697846804KKAXA,697846804KKMY2,697846804KKCXE,697846804JBAWA,697846804JBMX2,697846804JBCWE,697846804RSAZ5,
697846804RSMZV,697846804RSCZ9,697846804WSAZW,697846804WSM2R,697846804WSC25,697846804TWAZT,697846804TWM2N,
697846804TWC22

Clasificación (CLASE) / *Clasification (CLASS):* Producto sanitario Clase I no estéril (anexo VIII regla 1) / *class I not-sterile medical device(anexo VIII regla 1)*

Especificaciones comunes/Common specifications:

No existen especificaciones communes aplicables/ There are no applicable common specifications

La conformidad del producto se declara en base al cumplimiento de los requisitos generales de seguridad y funcionamiento establecidos en el Anexo I del Reglamento (UE) 2017/745, así como a la aplicación de las normas armonizadas pertinentes, en particular EN ISO 12870:2018 (Monturas para gafas. Requisitos y métodos de ensayo), junto con las disposiciones de gestión de riesgos conforme a ISO 14971 y demás requisitos aplicables.

The conformity of the product is declared based on compliance with the General Safety and Performance Requirements set out in Annex I of Regulation (EU) 2017/745, as well as the application of the relevant harmonized standards, in particular EN ISO 12870:2018 (Ophthalmic optics – Spectacle frames – Requirements and test methods), together with risk management according to ISO 14971 and other applicable requirements.

Organismo Notificado/Notified Body

No aplica, producto sanitario de Clase I sin intervención de organismo notificado/ Not applicable, Class I medical device without intervention of notified body.

Información complementaria/Additional Information

Normas armonizadas de referencia / *harmonized standards:*

Generales/*generals*

- EN ISO 14971: 2012. / EN ISO 15223-1:2016 / EN 1041:2008 + A1-2013 / EN ISO10993-1:2009 +AC:2010 / EN 62366:2008 / ISO 13485:2016

Específicas del producto / *Specifics of the product:*

- EN ISO 12870 Monturas de gafas /*Spectacle frames*

DECLARACIÓN UE DE CONFORMIDAD / EU DECLARATION OF CONFORMITY

REGLAMENTO (UE) 2017/745 DEL PARLAMENTO Y DE LA COMISIÓN DE LA UNIÓN EUROPEA

del 5 de abril de 2017 sobre los PRODUCTOS SANITARIOS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. of 5 April 2017 on MEDICAL DEVICES



Signed on behalf of: Superb Vision International Trading (Hangzhou) Co., Ltd.

超视国际贸易(杭州)有限公司
SUPERB VISION INTERNATIONAL TRADING (HANGZHOU) CO., LTD.

Place and date: Hangzhou (China), March 26th, 2026

ep.

Name: Dai Chengyi

Position: General Manager

Signature:

Dai Chengyi