

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Carclo Technical Plastics (Taicang) Co.,Ltd
No.8 Xi Xin Road, Chengxiang Town, Taicang, Jiangsu
Province, P.R China,215411.

Trademark: /

SRN: Not available yet

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN: DE-AR-000000087

Trade name: /

Product name: SPECTACLES

Product code / Catalogue number: See attachment

Basic UDI: 6976289705748JA

Classification acc. to MDR Ax. VIII: Class 1, rule 1

Applied Standard & Common Specification: ENISO12870:2016; ENISO8980-1:2017
ENISO8980-3:2022; ENISO8980-4:2006

Conformity assessment procedure: Annex II + Annex III of MDR;

CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), of the Directive 2011/65/EU and of the Directive (EU) 2015/863. All supporting documentations are retained under the premises of the manufacturer.

Yin Guihua

Quality Manager



Taicang, Jan.26. 2024

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Attachment:

Part NO#	Part Name	Part NO#	Part Name
3146	HYPER MICRO SPECS X4 OU NOCOAT	4158	H/EYE +10 45MM BROWN UNCOATED
3147	HYPER MICRO SPECS X4 OD PLANNC	4159	H/EYE +10 45MM CRYSTAL UNCTD
3148	HYPER MICRO SPECS X4 PLANOOSNC	4160	H/EYE +10 49MM CRYSTAL UNCTD
3149	HYPER MICRO SPECS X5 OU NOCOAT	4161	H/EYE +10 BROWN UNCOATED
3150	HYPER MICRO SPECS X5 OD	4162	H/EYE +12 45MM BROWN UNCOATED
3151	HYPERCRO SPECS X5 PLANOOSNC	4163	H/EYE +12 45MM CRYSTAL UNCTD
3152	HYPER MICRO SPECS X6 OU NOCOAT	4164	H/EYE +12 49MM CRYSTAL UNCTD
3153	HYPER MICRO SPECS X6 ODPLAONC	4165	H/EYE +12 49MM BROWN UNCOATED
3154	HYPER MICRO SPECS X6 PLANOOSNC	4166	H/EYE +14 45MM BROWN UNCOATED
3155	HYPER MICRO SPECS X8 OU NOCOAT	4167	H/EYE +14 45MM CRYSTAL UNCTD
3156	HYPER MICRO SPECS X8 ODPLANOC	4168	H/EYE +14 49MM CRYSTAL UNCTD
3157	HYPER MICRO SPECS X8 PLANOOSNC	4169	H/EYE +14 49MM BROWN UNCOATED
3158	HYPER MICRO SPECS X10 OU NOCT	4175	+4 1/4 PRISMSPEC 43-24 UNCTD
3159	HYPER MICRO SPECS X10 ODPLANOC	4177	+6 1/4 PRISMSOEC 43-24 UNCTD
3160	HYPER MICRO SPEC X10 PLANO OSNC	4179	+8 1/4 43-24 UNCTD
3161	HYPER MICROSPEC X12 OU UNCOATED	4181	+10 1/4 PRISMSPEC 43-24 UNCTD
3162	HYPER MICROSPEC X12 OD PLANO NC	4183	+12 1/4 PRISMSPEC 43-24 UNCTD
3163	HYPER MICROSPEC X12 PLANO OSNC	4185	+14 1/4 PRISMSPEC 43-24 UNCTD
35738R1	RAYLITE DUO LED HANDLE SHORT SPRING	5343R10	50MM HYP/CLR U/C UNCOAT X4
35739R1	RAYLITE DUO LED HANDLE LONG SPRING	5344R10	50MM HYP/CLR U/C UNCOAT X5
4146	H/EYE +4 45MM BROWN UNCTD	5345R10	50MM HYP/CLR U/C UNCOAT X6
4147	H/EYE +4 45MM CRYSTAL UCTD	5347R10	50MM HYP/CLR U/C UNCOAT X8
4148	H/EYE +4 49MM CRYSTAL UCTD	5371R10	65mm hyperocular 4x
4149	H/EYE +4 49MM BROWN UNCOATED	5372R10	65mm hyperocular 5x
4150	H/EYE +6 45MM BROWN UNCOATED	5373R10	65mm hyperocular 6x
4151	H/EYE +6 45MM CRYSTAL UNCOATED	5374R10	65mm hyperocular 8x
4152	H/EYE +6 49MM CRYSTAL UNCOATED	5375R10	65MM HYPEROCULAR 10X
4153	H/EYE +6 49MM BROWN UNCOATED	5376R10	65MM HYPEROCULAR 12X
4154	H/EYE +8 45MM BROWN UNCOATED	4090	SPECTACLE BINOCULAR TINT FAR
4155	H/EYE +8 45MM CRYSTAL UNCOATED	4090/02	SPECTACLE BINOCULAR CLEAR FAR
4156	H/EYE +8 49MM CRYSTAL UNCOATED	VFO4090/02	OPTELEC POWERTV GLASSES
4157	H/EYE +8 49MM BROWN UNCOATED		

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Yin Guihua
Quality Manager



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