



Name of manufacturer **Aoyama Optical Germany GmbH
Ahornstr. 11, 14482 Potsdam
Germany**

Single Registration Number (SRN) **DE-MF-000010836**

We declare under sole responsibility that the product

Name of product **East Spectacle Frames with sun protection / Models see Annex**

Basic UDI-DI **see Annex**

Nomenclature **UMDNS Code (ECRI) 11-667, GMDN Code 32816, EMDN Code see Annex**

Risk class **Class I – non sterile, no measuring function**

Conformity assessment procedure **pursuant to article 52 (7) for medical devices**

conforms with the following regulations:

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices

Complies with European standard DIN EN ISO 12870:2018-07

Risk category **Category I**

Conformity assessment procedure **internal production control (module A) set out in annex IV**

and conforms with the following regulations:

Regulation (EU) 2016/425 on personal protective equipment

Complies with European standard DIN EN ISO 12312-1:2023-07

and conforms with the following regulations:

Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

We operate a systematic procedure to monitor the product after placing it on the market.

Potsdam, 29.08.2024

Place and date of issue



Thomas Akiyama
CEO

Thomas Akiyama
MDR Responsible Person



Annex

Modellnummer/Farbe/Größe/Farbbeschreibung/ item no./col./size/description	EMDN Code	GMN-Code Basic-UDI-DI	GTIN-Code UDI-DI
EA 6001 01 48 burgundy-grey with suncli	Q02100202	4050551020402MH	405055105119
EA 6002 01 55 white with sunclip	Q02100202	4050551020402MH	405055105122
EA 6002 02 55 leopard with sunclip	Q02100202	4050551020402MH	405055105123
EA 6002 03 55 dk tortoise with sunclip	Q02100202	4050551020402MH	405055105124
EA 6003 01 53 rosé with sunclip	Q02100202	4050551020402MH	405055105125
EA 6003 02 53 violet ozean with sunclip	Q02100202	4050551020402MH	405055105126
EA 6003 03 53 brown green with sunclip	Q02100202	4050551020402MH	405055105127
EA 8003 01 58 black structure POL	Q02100202	4050551020402MH	405055104884
EA 8003 02 58 black POL	Q02100202	4050551020402MH	405055104885
EA 8003 03 58 havanna structure POL	Q02100202	4050551020402MH	405055104886
EA 8004 01 58 black structure POL	Q02100202	4050551020402MH	405055104887
EA 8004 02 58 black POL	Q02100202	4050551020402MH	405055104888
EA 8004 03 58 havanna POL	Q02100202	4050551020402MH	405055104889
EA 8005 02 63 dark blue POL	Q02100201	4050551010402M6	405055105055
EA 8005 03 63 dark brown POL	Q02100201	4050551010402M6	405055105056
EA 8006 01 62 aubergine-gold POL	Q02100201	4050551010402M6	405055105057
EA 8006 02 62 dark olive-brown POL	Q02100201	4050551010402M6	405055105058
EA 8006 03 62 black-silver POL	Q02100201	4050551010402M6	405055105059
EA 8007 01 54 brown gradient	Q02100202	4050551020402MH	405055104584
EA 8007 02 54 violet gradient	Q02100202	4050551020402MH	405055104585
EA 8007 03 54 rosé gradient	Q02100202	4050551020402MH	405055104586
EA 8007 04 54 ivory gradient	Q02100202	4050551020402MH	405055104587
EA 8008 01 58 dark havanna	Q02100202	4050551020402MH	405055105287
EA 8008 02 58 grey smoke	Q02100202	4050551020402MH	405055105288
EA 8008 03 58 brown smoke	Q02100202	4050551020402MH	405055105289
EA 8009 01 60 dark brown-light brown	Q02100201	4050551010402M6	405055105290
EA 8009 02 60 dark blue-light blue	Q02100201	4050551010402M6	405055105291
EA 8009 03 60 black	Q02100201	4050551010402M6	405055105292
EA 8010 01 58 dark brown/milky dk brown	Q02100201	4050551010402M6	405055105293
EA 8010 02 58 dark blue/dark blue	Q02100201	4050551010402M6	405055105294
EA 8010 03 58 black/milky cold grey	Q02100201	4050551010402M6	405055105295
EA 8014 02 57 grey smoke	Q02100202	4050551020402MH	405055105421
EA 8014 03 57 white black havanna	Q02100202	4050551020402MH	405055105422
EA 8015 02 60 grey smoke	Q02100202	4050551020402MH	405055105424
EA 8015 03 60 brown smoke	Q02100202	4050551020402MH	405055105425
EA 8016 01 57 black matt/black	Q02100201	4050551010402M6	405055105236
EA 8016 02 57 gun matt/dark grey	Q02100201	4050551010402M6	405055105237
EA 8016 03 57 silver matt/black	Q02100201	4050551010402M6	405055105238
EA 8017 01 59 black matt/gold matt	Q02100201	4050551010402M6	405055105239
EA 8017 02 59 gun matt/silver matt	Q02100201	4050551010402M6	405055105240
EA 8017 03 59 silver matt/black matt	Q02100201	4050551010402M6	405055105241
EA 8018 01 55 black matt/black	Q02100201	4050551010402M6	405055105210



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EA 8018 02 55 dark gun/dark grey	Q02100201	4050551010402M6	405055105211
EA 8018 03 55 dark brown	Q02100201	4050551010402M6	405055105212
EA 8019 03 54 dark brown	Q02100201	4050551010402M6	405055105215
EA 8020 02 60 grey grad-white-lt brown	Q02100202	4050551020402MH	405055105205
EA 8021 01 62 black-grey-black-white	Q02100202	4050551020402MH	405055105207
EA 8021 02 62 red grad-orange-dk blue	Q02100202	4050551020402MH	405055105208
EA 8021 03 62 havanna	Q02100202	4050551020402MH	405055105209
EA 8026 01 54 green white frozen	Q02100202	4050551020402MH	405055106478
EA 8026 02 54 white snake pattern	Q02100202	4050551020402MH	405055106479
EA 8026 02 54 white snake pattern ltd.	Q02100202	4050551020402MH	405055106479
EA 8026 03 54 brown grey nacre	Q02100202	4050551020402MH	405055106480
EA 8027 01 57 grey gradient	Q02100202	4050551020402MH	405055106481
EA 8027 01 57 grey gradient ltd.	Q02100202	4050551020402MH	405055106481
EA 8027 02 57 black/dark brown matt effect	Q02100202	4050551020402MH	405055106482
EA 8027 03 57 brown grey nacre	Q02100202	4050551020402MH	405055106483
EA 8035 02 48 burgundy+black ClipOn	Q02100202	4050551020402MH	405055108992
EA 8039 02 48 purple clear	Q02100202	4050551020402MH	405055109482
EA 8040 02 49 red mat/red	Q02100202	4050551020402MH	405055110466
EA 8041 02 52 burgundy red mt/burgundy	Q02100202	4050551020402MH	405055110469
EA 8042 01 54 black mat/black	Q02100202	4050551020402MH	405055110471
EA 8042 02 54 brown mat/brown	Q02100202	4050551020402MH	405055110472
EA 8042 03 54 blue mat/blue	Q02100202	4050551020402MH	405055110473
EA 8043 01 52 deep black mt/black-silv.+ ClipOn	Q02100202	4050551020402MH	405055111361
EA 8043 02 52 dk blue mat/blue-silver+ ClipOn	Q02100202	4050551020402MH	405055111362
EA 8043 03 52 havanna brown/br.-silver+ ClipOn	Q02100202	4050551020402MH	405055111363
EA 8044 01 49 deep black-blue mt/bl.-sl + ClipOn	Q02100202	4050551020402MH	405055111364
EA 8044 02 49 dk grey-lt grey mt/gun-sl + ClipOn	Q02100202	4050551020402MH	405055111365
EA 8044 03 49 dk blue-lt blue/blue-rosé + ClipOn	Q02100202	4050551020402MH	405055111366
EA 8045 01 53 slate grey mt/gun-silver	Q02100202	4050551020402MH	405055111409
EA 8045 02 53 black-blue mat/blue-silv.	Q02100202	4050551020402MH	405055111410
EA 8045 03 53 black-green-grey/black-gd	Q02100202	4050551020402MH	405055111411
EA 8046 01 55 deep black mat	Q02100201	4050551020402MH	405055113486
EA 8046 02 55 dk grey mt/green mt	Q02100201	4050551020402MH	405055113487
EA 8046 03 55 havanna brown mat	Q02100201	4050551020402MH	405055113488
EA 8047 01 56 deep black mat	Q02100201	4050551020402MH	405055113489
EA 8047 02 56 dk blue mat	Q02100201	4050551020402MH	405055113490
EA 8047 03 56 dk grey mt/blue mat	Q02100201	4050551020402MH	405055113491
EA 8048 01 53 bordeaux-black grad. mat	Q02100201	4050551020402MH	405055113492
EA 8048 02 53 grey taupe mat	Q02100201	4050551020402MH	405055113493
EA 8048 03 53 dark blue mat	Q02100201	4050551020402MH	405055113494
EA COAST 01 61 real silver	Q02100201	4050551010402M6	405055105479
EA YAKSHI 01 61 real gold	Q02100201	4050551010402M6	405055105480