



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 **Makellos 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, 11.08.2025

Place and date of issue


Thomas Akiyama
CEO


Thomas Akiyama
MDR Responsible Person



Annex

Modellnummer/Farbe/Größe/Farbeschreibung/ item no./col./size/description	EMDN Code	GMN-Code Basic-UDI-DI	GTIN-Code UDI-DI
ME 7000 01 50 gold	Q02100201	4050551010402M6	405055108389
ME 7000 02 50 silver	Q02100201	4050551010402M6	405055108390
ME 7001 01 52 gold	Q02100201	4050551010402M6	405055108391
ME 7001 02 52 silver	Q02100201	4050551010402M6	405055108392
ME 7002 01 52 gold	Q02100201	4050551010402M6	405055108393
ME 7002 02 52 silver	Q02100201	4050551010402M6	405055108394
ME 7003 01 58 racing silver mat	Q02100201	4050551010402M6	405055109412
ME 7003 02 58 dark gun mat	Q02100201	4050551010402M6	405055109413
ME 7004 01 58 dusk gun mat	Q02100201	4050551010402M6	405055109415
ME 7004 02 58 pale gold	Q02100201	4050551010402M6	405055109416
ME 7004 03 58 khaki green mat	Q02100201	4050551010402M6	405055109417
ME 7005 01 59 pale gold mat	Q02100201	4050551010402M6	405055109418
ME 7005 02 59 brilliant silver	Q02100201	4050551010402M6	405055109419
ME 7005 03 59 gun grey	Q02100201	4050551010402M6	405055109420
ME 7006 01 61 moonlight blue	Q02100201	4050551010402M6	405055109421
ME 7006 02 61 silver mat	Q02100201	4050551010402M6	405055109422
ME 7006 03 61 dark gun	Q02100201	4050551010402M6	405055109423
ME 7007 01 63 pale gold	Q02100201	4050551010402M6	405055109424
ME 7007 02 63 coffee brown mat	Q02100201	4050551010402M6	405055109425
ME 7007 03 63 ocean grey mat	Q02100201	4050551010402M6	405055109426
ME 7008 01 57 night black	Q02100201	4050551010402M6	405055109427
ME 7008 02 57 brilliant silver	Q02100201	4050551010402M6	405055109428
ME 7008 03 57 navy blue	Q02100201	4050551010402M6	405055109429
ME 7009 01 57 gun grey mat	Q02100201	4050551010402M6	405055109430
ME 7009 02 57 khaki green	Q02100201	4050551010402M6	405055109431
ME 7009 03 57 gold sand	Q02100201	4050551010402M6	405055109432
ME 7010 01 59 night black	Q02100201	4050551010402M6	405055109433
ME 7010 02 59 pale gold mat	Q02100201	4050551010402M6	405055109434
ME 7010 03 59 dark blue mat	Q02100201	4050551010402M6	405055109435
ME 7011 01 58 white gold mat	Q02100201	4050551010402M6	405055109436
ME 7011 02 58 midnight black mat	Q02100201	4050551010402M6	405055109437
ME 7011 03 58 gun grey	Q02100201	4050551010402M6	405055109438
ME 7012 01 58 gold mat-havanna	Q02100203	4050551030402MU	405055109439
ME 7012 02 58 silver mat-black	Q02100203	4050551030402MU	405055109440
ME 7012 03 58 black-grey milky	Q02100203	4050551030402MU	405055109441
ME 7013 01 59 racing silver mat	Q02100201	4050551010402M6	405055109442
ME 7013 02 59 olive green mat	Q02100201	4050551010402M6	405055109443
ME 7013 03 59 pale gold mat	Q02100201	4050551010402M6	405055109444
ME 7014 01 50 gun grey mat	Q02100201	4050551010402M6	405055109445
ME 7014 02 50 racing silver mat	Q02100201	4050551010402M6	405055109446
ME 7014 03 50 arctic blue-gold	Q02100201	4050551010402M6	405055109447



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ME 7015 01 54 grey milky/gun	Q02100203	4050551030402MU	405055109448
ME 7015 02 54 black-blue havanna/gold	Q02100203	4050551030402MU	405055109449
ME 7016 01 57 black/silver	Q02100203	4050551030402MU	405055109450
ME 7016 02 57 havanna/gold mat	Q02100203	4050551030402MU	405055109451
ME 7016 03 57 grey stripes/gun	Q02100203	4050551030402MU	405055109452
ME 7017 01 58 black/silver	Q02100203	4050551030402MU	405055109453
ME 7017 02 58 havanna-grey grad./gold	Q02100203	4050551030402MU	405055109454
ME 7017 03 58 dark blue/gun	Q02100203	4050551030402MU	405055109455
ME 7018 01 48 havanna-brown/gold	Q02100203	4050551030402MU	405055109456
ME 7018 02 48 grey clear/silver	Q02100203	4050551030402MU	405055109457
ME 7018 03 48 black/havanna/silver	Q02100203	4050551030402MU	405055109458
ME 7022 01 56 midnight black	Q02100202	4050551020402MH	405055113274
ME 7022 02 56 dark grey	Q02100202	4050551020402MH	405055113275
ME 7022 03 56 milky green	Q02100202	4050551020402MH	405055113276
ME 7023 01 61 light gun	Q02100201	4050551010402M6	405055113277
ME 7023 02 61 midnight black	Q02100201	4050551010402M6	405055113278
ME 7023 03 61 light gold	Q02100201	4050551010402M6	405055113279
ME 7024 01 54 silver	Q02100201	4050551010402M6	405055113280
ME 7024 02 54 gun brushed	Q02100201	4050551010402M6	405055113281
ME 7024 03 54 blue mat	Q02100201	4050551010402M6	405055113282
ME 7025 01 54 deep black	Q02100202	4050551020402MH	405055113283
ME 7025 02 54 ocean blue	Q02100202	4050551020402MH	405055113284
ME 7025 03 54 opal green	Q02100202	4050551020402MH	405055113285
ME 7026 01 54 deep black	Q02100202	4050551020402MH	405055113286
ME 7026 02 54 nude milky	Q02100202	4050551020402MH	405055113287
ME 7026 03 54 red transparent	Q02100202	4050551020402MH	405055113288
ME 7027 01 47 deep black	Q02100202	4050551020402MH	405055113289
ME 7027 02 47 ocean blue	Q02100202	4050551020402MH	405055113290
ME 7027 03 47 dark grey	Q02100202	4050551020402MH	405055113291
ME 7028 01 54 deep black	Q02100202	4050551020402MH	405055113292
ME 7028 02 54 milky dark blue	Q02100202	4050551020402MH	405055113293
ME 7028 03 54 anthrazit	Q02100202	4050551020402MH	405055113294
ME 7029 01 60 silver	Q02100201	4050551030102MD	405055113295
ME 7029 02 60 jet black mat	Q02100201	4050551030102MD	405055113296
ME 7029 03 60 rosé gold	Q02100201	4050551030102MD	405055113297
ME 7030 01 55 deep black	Q02100202	4050551020402MH	405055113298
ME 7030 02 55 nude milky	Q02100202	4050551020402MH	405055113299
ME 7030 03 55 transparent purple	Q02100202	4050551020402MH	405055113300
ME 7031 01 55 night black	Q02100202	4050551020402MH	405055113301
ME 7031 02 55 milky brown demi	Q02100202	4050551020402MH	405055113302
ME 7031 03 55 opal green	Q02100202	4050551020402MH	405055113303
ME 7032 01 56 light gold	Q02100203	4050551030402MU	405055113304



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ME 7032 02 56 gun	Q02100203	4050551030402MU	405055113305
ME 7032 03 56 nut brown	Q02100203	4050551030402MU	405055113306
ME 7033 01 50 black-gold	Q02100201	4050551030102MD	405055113307
ME 7033 02 50 black-silver	Q02100201	4050551030102MD	405055113308
ME 7033 03 50 black-rosé gold	Q02100201	4050551030102MD	405055113309
ME 7034 01 59 night black	Q02100203	4050551030402MU	405055113310
ME 7034 02 59 black-silver brushed	Q02100203	4050551030402MU	405055113311
ME 7034 03 59 forest green	Q02100203	4050551030402MU	405055113312
ME 7035 01 57 night black	Q02100203	4050551030402MU	405055113313
ME 7035 02 57 black-silver brushed	Q02100203	4050551030402MU	405055113314
ME 7035 03 57 forest green	Q02100203	4050551030402MU	405055113315
ME 7036 01 53 night black	Q02100203	4050551030402MU	405055113316
ME 7036 02 53 black-gold	Q02100203	4050551030402MU	405055113317
ME 7036 03 53 ocean blue-silver	Q02100203	4050551030402MU	405055113318
ME 7037 01 58 light gun	Q02100201	4050551010402M6	405055113319
ME 7037 02 58 walnut brown mat	Q02100201	4050551010402M6	405055113320
ME 7037 03 58 deep black	Q02100201	4050551010402M6	405055113321
ME 7038 01 58 deep black	Q02100202	4050551020402MH	405055113322
ME 7038 02 58 milky green	Q02100202	4050551020402MH	405055113323
ME 7038 03 58 transparent dark grey	Q02100202	4050551020402MH	405055113324
ME 7039 01 59 night black mat	Q02100201	4050551010402M6	405055113325
ME 7039 02 59 brown mt.-light gold	Q02100201	4050551010402M6	405055113326
ME 7039 03 59 silver mat-silver	Q02100201	4050551010402M6	405055113327
ME 7040 01 58 gold	Q02100201	4050551010402M6	405055113328
ME 7040 02 58 silver	Q02100201	4050551010402M6	405055113329
ME 7040 03 58 black brushed	Q02100201	4050551010402M6	405055113330
ME 7041 01 60 gold	Q02100201	4050551010402M6	405055113331
ME 7041 02 60 gun brushed	Q02100201	4050551010402M6	405055113332
ME 7041 03 60 azure blue	Q02100201	4050551010402M6	405055113333
ME Adelheid - black-champagne	Q02100202	4050551020402MH	405055109017
ME BARBERINI 01 53 night blue-white-lt.blue	Q02100202	4050551020402MH	405055111313
ME BARBERINI 02 53 burgundy-beige-brown str.	Q02100202	4050551020402MH	405055111314
ME BARBERINI 03 53 black-nude-black-havanna	Q02100202	4050551020402MH	405055111315
ME Caroline 01 58 Mystik grey-white/Sakura	Q02100202	4050551020402MH	405055106968
ME FRIEDRICH 01 62 oliv - hellgrün Verlauf	Q02100202	4050551020402MH	405055105444
ME Friedrich Wilhelm	Q02100202	4050551020402MH	405055106183
ME Fritz - black-vintage mint	Q02100202	4050551020402MH	405055109018
ME Luise	Q02100202	4050551020402MH	405055106182
ME Luise AS	Q02100202	4050551020402MH	405055106936
ME SABABA 01 53 violet clear/light gold	Q02100202	4050551020402MH	405055110219
ME SABABA 02 53 ocean green/turquoise	Q02100202	4050551020402MH	405055110220
ME SABABA 03 53 fuchsia-clear/rosé gold	Q02100202	4050551020402MH	405055110221



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ME SOPHIE CHARL 01 57 havanna - pastellgelb	Q02100202	4050551020402MH	405055105445
ME ZERO 2.0 01 48 dark shadow	Q02100201	4050551010402M6	405055116402
ME ZERO 2.0 02 48 deep sea	Q02100201	4050551010402M6	405055116403