



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 **Madame 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
MD 8000 01 58 gold mat/white pattern	Q02100203	4050551030402MU	405055110646
MD 8000 02 58 silver/green milky	Q02100203	4050551030402MU	405055110647
MD 8000 03 58 blue-grey mat/white	Q02100203	4050551030402MU	405055110648
MD 8001 01 50 light gold/black	Q02100203	4050551030402MU	405055110649
MD 8001 02 50 silver/ blue	Q02100203	4050551030402MU	405055110650
MD 8001 03 50 rosé gold mat/nude milky	Q02100203	4050551030402MU	405055110651
MD 8001 04 50 rosé gold/turquoise	Q02100203	4050551030402MU	405055111397
MD 8001 05 50 light gold/black	Q02100203	4050551030402MU	405055111408
MD 8002 01 54 black pearly	Q02100202	4050551020402MH	405055110476
MD 8002 02 54 havanna/red	Q02100202	4050551020402MH	405055110477
MD 8002 03 54 orange clear/brown	Q02100202	4050551020402MH	405055110478
MD 8003 01 51 havanna/lt orange	Q02100202	4050551020402MH	405055110479
MD 8003 02 51 red/grey milky	Q02100202	4050551020402MH	405055110480
MD 8003 03 51 black-white/white	Q02100202	4050551020402MH	405055110481
MD 8004 01 55 rosé gold/black mat	Q02100201	4050551010402M6	405055110482
MD 8004 02 55 gold mt/red mt	Q02100201	4050551010402M6	405055110483
MD 8004 03 55 gold/blue mat	Q02100201	4050551010402M6	405055110484
MD 8005 01 56 rosé gold mat/rosé gold	Q02100201	4050551010402M6	405055110652
MD 8005 02 56 light gold	Q02100201	4050551010402M6	405055110653
MD 8005 03 56 gun mat/gun	Q02100201	4050551010402M6	405055110654
MD 8006 01 58 light gold mat	Q02100201	4050551010402M6	405055110596
MD 8006 02 58 greengold	Q02100201	4050551010402M6	405055110597
MD 8006 03 58 light gold	Q02100201	4050551010402M6	405055110598
MD 8007 01 51 lt grey clear-green glitt	Q02100202	4050551020402MH	405055110599
MD 8007 02 51 black-grey glitter	Q02100202	4050551020402MH	405055110600
MD 8007 03 51 lt rosé cl.-silver glitt	Q02100202	4050551020402MH	405055110601
MD 8008 01 55 gold	Q02100201	4050551010402M6	405055110565
MD 8008 02 55 lt rosé gold mat	Q02100201	4050551010402M6	405055110566
MD 8008 03 55 silver brushed	Q02100201	4050551010402M6	405055110567
MD 8009 01 53 black-wildlife-white	Q02100202	4050551020402MH	405055110582
MD 8009 02 53 black-white pattern	Q02100202	4050551020402MH	405055110583
MD 8009 03 53 grey-rosé-havanna grad.	Q02100202	4050551020402MH	405055110584
MD 8010 01 56 black/gold mat	Q02100203	4050551030402MU	405055110655
MD 8010 02 56 havanna pink/rosé gold	Q02100203	4050551030402MU	405055110656
MD 8010 03 56 havanna brown/gold	Q02100203	4050551030402MU	405055110657
MD 8011 01 52 grey-blue milky	Q02100202	4050551020402MH	405055110585
MD 8011 02 52 mallow milky	Q02100202	4050551020402MH	405055110586
MD 8011 03 52 red clear gradient	Q02100202	4050551020402MH	405055110587
MD 8012 01 56 night blue-white-lt.blue	Q02100202	4050551020402MH	405055111316
MD 8012 02 56 burgundy-beige-brown str.	Q02100202	4050551020402MH	405055111317
MD 8012 03 56 black-nude-black-havanna	Q02100202	4050551020402MH	405055111318
MD 8013 01 56 deep black-light gold	Q02100201	4050551010402M6	405055111286



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MD 8013 02 56 black green-copper	Q02100201	4050551010402M6	405055111287
MD 8013 03 56 chestnut brown-gun	Q02100201	4050551010402M6	405055111288
MD 8014 01 55 grey-pink gradient	Q02100202	4050551020402MH	405055112267
MD 8014 02 55 pink-brown gradient	Q02100202	4050551020402MH	405055112268
MD 8014 03 55 blue floral	Q02100202	4050551020402MH	405055112269
MD 8015 01 48 warm brown	Q02100202	4050551020402MH	405055112189
MD 8015 02 48 dk rose - red/black patt.	Q02100202	4050551020402MH	405055112190
MD 8015 03 48 pearlgrey-greybr. havanna	Q02100202	4050551020402MH	405055112191
MD 8016 01 54 havanna-beige/bronze	Q02100202	4050551030402MU	405055112192
MD 8016 02 54 grey multicolor/gun mat	Q02100202	4050551030402MU	405055112193
MD 8016 03 54 warm green str./light gd.	Q02100202	4050551030402MU	405055112194
MD 8017 01 54 light gold	Q02100201	4050551010402M6	405055112288
MD 8017 02 54 roségold mat	Q02100201	4050551010402M6	405055112289
MD 8017 03 54 moss green	Q02100201	4050551010402M6	405055112290
MD 8018 01 58 light gold	Q02100201	4050551010402M6	405055112291
MD 8018 02 58 roségold brushed	Q02100201	4050551010402M6	405055112292
MD 8018 03 58 dark violet	Q02100201	4050551010402M6	405055112293
MD 8019 01 55 gold-jet black	Q02100203	4050551030402MU	405055113066
MD 8019 02 55 silver-purple transp.	Q02100203	4050551030402MU	405055113067
MD 8019 03 55 gun-light green transp.	Q02100203	4050551030402MU	405055113068
MD 8020 01 51 night black	Q02100202	4050551020402MH	405055113086
MD 8020 02 51 red-gr.-purple floral gr.	Q02100202	4050551020402MH	405055113087
MD 8020 03 51 white clear	Q02100202	4050551020402MH	405055113088
MD 8021 01 53 gold-night black	Q02100203	4050551030402MU	405055113069
MD 8021 02 53 gun-grey clear	Q02100203	4050551030402MU	405055113070
MD 8021 03 53 silver mat-havanna (ECO)	Q02100203	4050551030402MU	405055113071
MD 8022 01 57 rosé transp.-roségold ECO	Q02100202	4050551020402MH	405055113731
MD 8022 02 57 blue-gold patt.-gold	Q02100202	4050551020402MH	405055113732
MD 8022 03 57 berry red gradient-gun	Q02100202	4050551020402MH	405055113733
MD 8023 01 56 bl.-grey-pink gradient-gd	Q02100202	4050551020402MH	405055113734
MD 8023 02 56 brown-purple transp.-gold	Q02100202	4050551020402MH	405055113735
MD 8023 03 56 ocean blue-gun	Q02100202	4050551020402MH	405055113736
MD 8024 01 54 purple multicolor-gold br	Q02100202	4050551030402MU	405055113737
MD 8024 02 54 chestnut brown str.-gold	Q02100202	4050551030402MU	405055113738
MD 8024 03 54 forest green stripes-silv	Q02100202	4050551030402MU	405055113739
MD 8025 01 55 brown stripes gradient	Q02100202	4050551020402MH	405055113750
MD 8025 02 55 sky blue gradient	Q02100202	4050551020402MH	405055113751
MD 8025 03 55 rosé-red stripes gradient	Q02100202	4050551020402MH	405055113752
MD 8027 01 52 purple milky	Q02100202	4050551020402MH	405055113809
MD 8027 02 52 green milky havana	Q02100202	4050551020402MH	405055113810
MD 8027 03 52 black brown glitter	Q02100202	4050551020402MH	405055113811