



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 **F2 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, 30.08.2024

Place and date of issue


Thomas Akiyama
CEO


Thomas Akiyama
MDR Responsible Person



Annex

Model	EMDN Code	GMN-Code Basic-UDI-DI	GTIN-Code UDI-DI
F2 7000 01 62 black mat-yellow mat POL	Q02100202	4050551020402MH	4050551139090
F2 7000 02 62 black mat-red mat POL	Q02100202	4050551020402MH	4050551139106
F2 7000 03 62 jet black POL	Q02100202	4050551020402MH	4050551139113
F2 7001 01 59 jet black-red mat POL	Q02100202	4050551020402MH	4050551139120
F2 7001 02 59 clear-light blue mat POL	Q02100202	4050551020402MH	4050551139137
F2 7001 03 59 dark grey tr.-black mat POL	Q02100202	4050551020402MH	4050551139144
F2 7001 04 59 black mat	Q02100202	4050551020402MH	4050551152808
F2 7002 01 64 black mat-lt. blue mat POL	Q02100202	4050551020402MH	4050551139151
F2 7002 02 64 grey tr.-black mat POL	Q02100202	4050551020402MH	4050551139168
F2 7002 03 64 turquoise-black mat POL	Q02100202	4050551020402MH	4050551139175
F2 7003 01 67 jet black-black mat	Q02100202	4050551020302MC	4050551139182
F2 7003 02 67 black mat-red mat	Q02100202	4050551020302MC	4050551139199
F2 7003 03 67 white mat-black mat	Q02100202	4050551020302MC	4050551139205
F2 7004 01 66 jet black-black mat	Q02100202	4050551020302MC	4050551139212
F2 7004 02 66 black mat-red mat	Q02100202	4050551020302MC	4050551139229
F2 7004 03 66 white mat-black mat	Q02100202	4050551020302MC	4050551139236
F2 7005 01 70 jet black-black mat	Q02100202	4050551020302MC	4050551139243
F2 7005 02 70 black mat-red mat	Q02100202	4050551020302MC	4050551139250
F2 7005 03 70 clear-light blue mat	Q02100202	4050551020302MC	4050551139267
F2 7005 04 70 jet black-black mat	Q02100202	4050551020302MC	4050551152815
F2 7006 01 60 black-berry red POL	Q02100202	4050551020402MH	4050551139274
F2 7006 02 60 black-purple POL	Q02100202	4050551020402MH	4050551139281
F2 7006 03 60 black-apple green POL	Q02100202	4050551020402MH	4050551139298
F2 7007 01 61 jet black mt-blue mt POL	Q02100202	4050551020402MH	4050551140416
F2 7007 02 61 wht mt-black mt POL	Q02100202	4050551020402MH	4050551140423
F2 7008 01 59 jet black mt-lt. green mt POL	Q02100202	4050551020402MH	4050551141949
F2 7008 02 59 navy blue mat-yellow mt POL	Q02100202	4050551020402MH	4050551141956
F2 7009 01 57 jet black mat-lt. blue mt POL	Q02100202	4050551020402MH	4050551141963
F2 7009 02 57 taupe mt transp.-yell. Mt POL	Q02100202	4050551020402MH	4050551141970
F2 7010 01 61 frosty mat-gold brushed POL	Q02100202	4050551020402MH	4050551141987
F2 7010 02 61 slate grey-silver brushed POL	Q02100202	4050551020402MH	4050551141994
F2 7011 01 51 berry red mat POL	Q02100202	4050551020402MH	4050551142007
F2 7011 02 51 light grey mat POL	Q02100202	4050551020402MH	4050551142014
F2 7012 01 54 dark blue mat POL	Q02100202	4050551020402MH	4050551142021
F2 7012 02 54 green transparent POL	Q02100202	4050551020402MH	4050551142038
F2 7013 01 74 jet black mt-green mt POL	Q02100202	4050551020102M2	4050551140430
F2 7013 02 74 white mt-blue mat POL	Q02100202	4050551020102M2	4050551140447
F2 7014 01 73 jet black-lt blue mt	Q02100202	4050551020302MC	4050551140805
F2 7014 02 73 light grey-black mt	Q02100202	4050551020302MC	4050551140812
F2 7014 03 73 light purple-purple mt	Q02100202	4050551020302MC	4050551140829
F2 7014 04 69 black mat	Q02100202	4050551020302MC	4050551152822