



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 **Suri Frey 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	Basic-UDI-DI	EAN-Code
SF 6000 01 50 red-gold	Q02100203	4050551030402MU	405055108616
SF 6000 02 50 brown-gold	Q02100203	4050551030402MU	405055108617
SF 6000 03 50 blue-gun	Q02100203	4050551030402MU	405055108618
SF 6001 01 50 green-purple	Q02100202	4050551020402MH	405055108625
SF 6001 02 50 havanna	Q02100202	4050551020402MH	405055108626
SF 6001 03 50 rose havanna	Q02100202	4050551020402MH	405055108627
SF 6002 01 52 green-black matt	Q02100202	4050551020402MH	405055108628
SF 6002 02 52 brown-pink matt	Q02100202	4050551020402MH	405055108629
SF 6002 03 52 blue-black matt	Q02100202	4050551020402MH	405055108630
SF 6003 01 55 brown	Q02100202	4050551020402MH	4050551086318
SF 6003 02 55 olive	Q02100202	4050551020402MH	4050551086325
SF 6003 03 55 blue	Q02100202	4050551020402MH	4050551086332
SF 6004 01 52 havanna	Q02100202	4050551020402MH	405055108634
SF 6004 02 52 red	Q02100202	4050551020402MH	405055108635
SF 6004 03 52 grey	Q02100202	4050551020402MH	405055108636
SF 6005 01 50 yellow havanna	Q02100203	4050551030402MU	405055108500
SF 6005 02 50 black grey sparkle	Q02100203	4050551030402MU	405055108501
SF 6005 03 50 rose olive sparkle	Q02100203	4050551030402MU	405055108502
SF 6006 01 50 blue matt	Q02100202	4050551020402MH	405055108467
SF 6006 02 50 purple	Q02100202	4050551020402MH	405055108468
SF 6006 03 50 brown	Q02100202	4050551020402MH	405055108469
SF 6007 01 50 brown stripes	Q02100203	4050551030402MU	405055108470
SF 6007 02 50 blue	Q02100203	4050551030402MU	405055108471
SF 6007 03 50 havanna	Q02100203	4050551030402MU	405055108472
SF 6008 01 52 beige/brown	Q02100203	4050551030402MU	405055108473
SF 6008 02 52 blue	Q02100203	4050551030402MU	405055108474
SF 6008 03 52 black	Q02100203	4050551030402MU	405055108475
SF 6009 01 56 black	Q02100202	4050551020402MH	405055108476
SF 6009 02 56 grey havanna	Q02100202	4050551020402MH	405055108477
SF 6009 03 56 brown/blue	Q02100202	4050551020402MH	405055108478
SF 6010 01 52 brown stripes	Q02100202	4050551020402MH	405055108479
SF 6010 02 52 havanna	Q02100202	4050551020402MH	405055108480
SF 6010 03 52 black	Q02100202	4050551020402MH	405055108481