



Name of manufacturer **Swiss Eye International GmbH
Nord-West Ring 14, 32832 Augustdorf
Germany**

Single Registration Number (SRN) **DE-MF-000008076**

We declare under sole responsibility that the product

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

Basic UDI-DI **See Annex**

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

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 EN ISO 12870

and conforms with the following regulations:

Regulation (EU) 2016/425 on personal protective equipment

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

Complies with European standard EN ISO 12312-1

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.

This declaration of conformity has a limit of validity of 10 years.

Augustdorf, 10.01.2023

Place and date of issue

SWISSEYE
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name
MDR Responsible Person Daniela
Diekmann



Anhang/Appendix Top Look frame with sunclip:

Basic UDI-DI 4046375F-PLA-FUL-ADL-F6 / EMDN Q02100202:

- 53100
- 53103
- 53114
- 53115
- 53117
- 53118
- 53119
- 53122
- 53125
- 53126
- 53127
- 53128
- 53129
- 53130
- 53131
- 53132
- 53133
- 53134
- 53135
- 53136

Basic UDI-DI 4046375F-MIX-FUL-ADL-VM / EMDN 02100203:

- 53116
- 53120
- 53121
- 53124
- 53137
- 53138
- 53139
- 53140
- 53142
- 53143
- 53144
- 53145

Datum: 18.10.24
Name PRRC: Daniel Dehmann
Unterschrift PRRC:



- 53146
- 53147
- 53148
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- 53150
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- 53166

Basic UDI-DI 4046375F-MIX-HAF-ADL-HR / EMDN Q02100203:

- 53123
- 53141

Datum: 18.12.24
Name PRRC: Daniela Dreksauer
Unterschrift PRRC: 