



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 / Models see Annex**

Basic UDI-DI **See appendix**

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

Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Complies with European standard EN ISO 12870

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
Swiss Eye International GmbH
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name
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name
MDR Responsible Person
Daniela Diekmann



Appendix CE Top Look:

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

- 7105
- 7106
- 7107
- 7108
- 7120
- 7121
- 7122
- 7124
- 7137
- 8729
- 8786
- 9917
- 9965
- 56002
- 57140
- 57142
- 57155
- 57156
- 57171
- 57181
- 57197
- 57198
- 57206
- 57251
- 57252
- 58100
- 58105
- 58106
- 58129
- 58146
- 58150
- 58177
- 59101
- 59115
- 59116
- 59117



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- 59118
 - 59119
 - 59121
 - 59122
 - 59125
 - 59127
 - 59128
 - 59134
 - 59138
 - 59139
 - 59143
 - 59144
 - 59152
 - 59154

Basic UDI-DI 4046375-F-PLA-HAF-ADL-3A / EMDN Q02100202:

- 57218

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

- 2119
- 2121
- 6032
- 6033
- 6039
- 8770
- 8776
- 8783
- 8798
- 8802
- 8812
- 9368
- 9381
- 9946
- 9947
- 9963
- 9967
- 9977
- 51100
- 51101



- 51103
- 51104
- 52101
- 52102
- 52103
- 52104
- 52105
- 52106
- 52107
- 52108
- 52109
- 52110
- 54229
- 54241
- 54247
- 54249
- 54250
- 54252
- 54253
- 54255
- 54256
- 54257
- 54258
- 54259
- 54260
- 54261
- 54262
- 54263
- 54264
- 54265
- 54266
- 54267
- 54268
- 54269
- 54270
- 54271
- 54272
- 54274
- 56001
- 56004



- 56005
- 56006
- 57143
- 57152
- 57153
- 57154
- 57160
- 57161
- 57173
- 57174
- 57177
- 57184
- 57185
- 57188
- 57196
- 57199
- 57200
- 57203
- 57204
- 57205
- 57207
- 57208
- 57209
- 57210
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- 57232



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- 59123
- 59126
- 59132
- 59141
- 59145
- 59146
- 59148
- 59153
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- 59157
- 59158
- 59159
- 59160
- 59161

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

- 4201



- 4205
- 6034
- 6035
- 6036
- 6037
- 6038
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- 7117
- 8780
- 8805
- 8813
- 54248
- 54251
- 54254
- 54273
- 57163
- 57179
- 57189
- 57201
- 57202
- 57212
- 57217
- 57220
- 57245
- 58120
- 58152
- 58154
- 58158
- 58167
- 58813
- 58814
- 59147
- 59149
- 59150
- 59151

Basic UDI-DI 4046375F-MIX-RL-ADL-X8 / EMDN Q02100203:

- 57192
- 57193



- 58140
- 58149

Basic UDI-DI 4046375F-MIX-FUL-KID-XU / EMDN Q02100203:

- 5139
- 52100
- 54233
- 54234
- 55100
- 55101
- 55102
- 55103
- 55104
- 55105
- 55106

Basic UDI-DI 4046375F-PLA-FUL-KID-HD / EMDN Q02100202:

- 59142