



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.


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Augustdorf, 10.01.2023

Place and date of issue

name
CEO Andreas Rückstein

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
- 9917
- 9965
- 56002
- 57140
- 57142
- 57155
- 57156
- 57171
- 57181
- 57197
- 57198
- 57206
- 58100
- 58105
- 58106
- 58129
- 58146
- 58150
- 59101
- 59115
- 59116
- 59117
- 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
- 8770
- 8776
- 8783
- 8798
- 8802
- 8812
- 9368
- 9381
- 9946
- 9947
- 9963
- 9967
- 9977
- 51100
- 51101
- 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
- 56001
- 56004
- 56005
- 56006
- 57143
- 57152
- 57153
- 57154
- 57160
- 57161
- 57173
- 57177
- 57184
- 57185
- 57188
- 57196
- 57199
- 57200
- 57203
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- 57205
- 57207
- 57208
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- 57210
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- 57221
- 57222
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- 57226
- 57227
- 57228
- 57229
- 57230
- 57231
- 57232
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- 57234
- 57235
- 57236
- 58108
- 58122
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- 58137
- 58141
- 58142
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- 58151
- 58153
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- 58168
- 58169
- 58170
- 58171
- 58172
- 58173
- 58174
- 58175
- 58176
- 59123
- 59126
- 59132
- 59141
- 59145
- 59146
- 59148
- 59153
- 59155
- 59157
- 59158

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

- 4201
- 4205
- 6034
- 6035
- 6036
- 6037
- 7117
- 8780
- 54248



- 54251
- 54254
- 57163
- 57179
- 57201
- 57202
- 57212
- 57217
- 57220
- 58120
- 58152
- 58154
- 58158
- 58167
- 58813
- 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

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

- 59142