



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, 22.07.2021

Place and date of issue

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name
MDR Responsible Person
Daniela Drzyzga



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



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- 59122
 - 59125
 - 59127
 - 59128
 - 59134
 - 59138
 - 59139
 - 59143
 - 59144

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



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- 54253
 - 54255
 - 54256
 - 54260
 - 54261
 - 54262
 - 56001
 - 56004
 - 56005
 - 56006
 - 57143
 - 57152
 - 57153
 - 57154
 - 57160
 - 57161
 - 57177
 - 57184
 - 57185
 - 57188
 - 57196
 - 57199
 - 57200
 - 57203
 - 57204
 - 57205
 - 57207
 - 57208
 - 57209
 - 57210
 - 57211
 - 57213
 - 57214
 - 57215
 - 57216
 - 57219
 - 57221
 - 57222
 - 58108
 - 58122



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- 58127
 - 58128
 - 58132
 - 58134
 - 58137
 - 58141
 - 58142
 - 58143
 - 58147
 - 58148
 - 58151
 - 58153
 - 58155
 - 58156
 - 59123
 - 59126
 - 59132
 - 59141
 - 59145
 - 59146

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

- 4201
- 4205
- 7117
- 8780
- 54248
- 54251
- 54254
- 57163
- 57179
- 57201
- 57202
- 57212
- 57217
- 57220
- 58120
- 58152
- 58154



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- 58813

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