



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  
Nord-West-Ring 14 · D-32832 Augustdorf  
Tel.: +49 (0) 5237 2316-0  
info@swisseye.com

name  
CEO Andreas Rückstein

  
**SWISSEYE**  
Swiss Eye International GmbH  
Nord-West-Ring 14 · D-32832 Augustdorf  
Tel.: +49 (0) 5237 2316-0  
info@swisseye.com

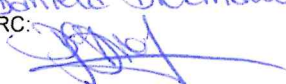
name  
MDR Responsible Person  
Daniela Diekmann



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
- 52111
- 52112
- 52113
- 56002
- 57140
- 57142
- 57155
- 57156
- 57159
- 57171
- 57181
- 57197
- 57198
- 57206
- 57251
- 57252
- 58100
- 58105
- 58106
- 58129
- 58146

Datum: 18.10.24  
Name PRRC: Daniela Diekmann  
Unterschrift PRRC: 



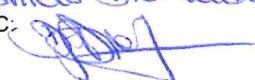
- 58150
- 58177
- 58184
- 59101
- 59115
- 59116
- 59117
- 59118
- 59119
- 59121
- 59122
- 59125
- 59127
- 59128
- 59134
- 59138
- 59139
- 59143
- 59144
- 59152
- 59154

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

- 57218

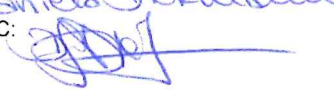
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- 2119
- 2121
- 6032
- 6033
- 6039
- 7115
- 8770
- 8776
- 8783
- 8798

Datum: 18.12.24  
Name PRRC: Daniela Dreksauer  
Unterschrift PRRC: 



- 8802
- 8808
- 8812
- 9368
- 9381
- 9840
- 9946
- 9947
- 9963
- 9967
- 9976
- 9977
- 51100
- 51101
- 51103
- 51104
- 52101
- 52102
- 52103
- 52104
- 52105
- 52106
- 52107
- 52108
- 52109
- 52110
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- 52118
- 52119
- 52120
- 52121
- 54229
- 54235
- 54240
- 54241

Datum: 18.10.24  
Name PRRC: Daniela Jekmann  
Unterschrift PRRC: 



- 54247
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- 54252
- 54253
- 54255
- 54256
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- 54258
- 54259
- 54260
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- 54264
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- 54269
- 54270
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- 54272
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- 54275
- 54276
- 57277
- 54278
- 56001
- 56004
- 56005
- 56006
- 57141
- 57143
- 57148
- 57152
- 57153
- 57154

Datum: 18.12.24  
Name PRRC: Daniela Odenmann  
Unterschrift PRRC:




- 57160
- 57161
- 57166
- 57173
- 57174
- 57176
- 57177
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- 57188
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- 57229
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- 57231
- 57232
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Datum: 18.12.24  
Name PRRC: Daniela Dreikmann  
Unterschrift PRRC: 



- 57234
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- 57236
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- 58119
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- 58124
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- 58128
- 58132
- 58134
- 58135
- 58137
- 58141

Datum: 18.12.24  
Name PRRC: Daniela Debusan  
Unterschrift PRRC: 



- 58142
- 58143
- 58144
- 58147
- 58148
- 58151
- 58153
- 58155
- 58156
- 58157
- 58161
- 58162
- 58163
- 58164
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- 58181
- 58182
- 58183
- 58185
- 58186
- 59123
- 59126
- 59132
- 59141
- 59145

Datum: 18.10.24  
Name PRRC: Daniela Diekmann  
Unterschrift PRRC:





- 59146
- 59148
- 59153
- 59155
- 59157
- 59158
- 59159
- 59160
- 59161

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

- 4201
- 4205
- 6034
- 6035
- 6036
- 6037
- 6038
- 7117
- 8780
- 8805
- 8813
- 54248
- 54251
- 54254
- 54273
- 57162
- 57163
- 57179
- 57189
- 57201
- 57202
- 57212
- 57217
- 57220
- 57245
- 58120

Datum: 18.12.24  
Name PRRC: Daniela Piekman  
Unterschrift PRRC: 



- 58152
- 58154
- 58158
- 58167
- 58813
- 58814
- 59147
- 59149
- 59150
- 59151

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

- 4183
- 9630
- 9893
- 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

Datum: 18.12.04  
Name PRRC: Daniela Dekusman  
Unterschrift PRRC: 