



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 **Swisseye sports-and tacticalglasses / 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
Swiss Eye International GmbH
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SWISSEYE
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name
MDR Responsible Person Daniela
Diekmann



Anhang/Appendix Swisseye:

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

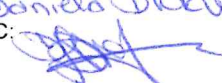
- Junior
- Paladin
- Rocker Pro
- Toddler

Basic UDI-DI 4046375F-PLA-HAF-KID-5H / EMDN Q02100202:

- Spin

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

- Ambient
- Cargo (RX)
- Chamäleon
- Cleanocean
- Cobra
- Concept M
- Concept M Re+
- Devil
- Drift
- Everyday
- Fly
- Freeride
- Freestyle
- F-Tac
- F-Tac Pro
- F-Tac Arctic
- Fun
- Gardosa 6C
- Grip
- G-Tac
- Guardian Arctic
- Guardian
- Guardian Sports
- Hurricane
- Joker
- Joy


Datum: 18.10.24
Name PRRC: Daniela Dreiermann
Unterschrift PRRC: 



- Kanjo Flex
- Life
- M-Cover (1-4)
- Net
- Notice
- Nucleo 6C
- Peak
- R-Tac
- Sense
- Tilton (RX)
- Tomcat
- Tracker
- Trail (RX)
- Win
- 3301
- 3303
- 3307
- 3308
- 3309
- 3310

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

- Anytime
- Apache
- Arrow (RX)
- Attac
- Blackhawk
- Blackhawk Pro
- Blackhawk Sports (RX)
- Dawn
- Gardosa Evolution M/P
- Gardosa Re+ / S (RX)
- Glace
- Iconic 2.0 (RX)
- Iconic 3.0
- Lancer
- Leisure

Datum: 18.12.24
Name PRRC: Daniela Dörmann
Unterschrift PRRC: 



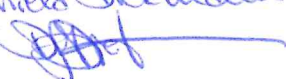
- Mantra (RX)
- Maverick
- M-Shield
- Nighthawk
- Nighthawk Pro
- Nighthawk Sports (RX)
- Novena / S (RX)
- Novena Re+ / S (RX)
- Nucleo
- Nucleo Re+
- Racer
- Raptor
- Raptor Pro
- Secret (RX)
- Signal (RX)
- Skyray
- Solena (RX)
- Speedway
- Sprint (RX)
- Stingray M/P
- Tilton Halfrim (RX)
- Venture
- View
- Wire (RX)

Basic UDI-DI 4046375F-MIX-FUL-ADL-VM / EMDN Q02100203:

- 3304
- 3305
- 3306
- 3311
- 3312
- 3313

Basic UDI-DI 4046375F-PLA-RL-ADL-LB / EMDN Q02100202:

- C-Shield / S (RX)
- Defense
- Outbreak / S
- Outbreak Evo / S
- Outbreak Luzzone / S

Datum: 18.12.24
Name PRRC: Daniel Dietmann
Unterschrift PRRC: 

Document No.
TDS-01-009-241218



EU-Konformitätserklärung/declaration
of conformity

-
- Speedster (RX)
 - Wave

Basic UDI-DI 4046375RR-PLA-FUL-ORG-RQ / EMDN Q0210030102:

- Freeride Bifo

Basic UDI-DI 4046375RR-PLA-HAF-ORG-DU / EMDN Q0210030102:

- Gardosa Re+ (S) Bifo
 - Glace Bifo
 - Nucleo Bifo
-

Datum: 18.10.24
Name PRRC: Daniels Oprekman
Unterschrift PRRC: 