



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, 22.07.2021

Place and date of issue

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name  
MDR Responsible Person Daniela Drzyzga



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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:

- Hurricane
- Concept M
- Concept M Re+
- Trail (RX)
- Chamäleon
- Notice
- Sense
- Tracker
- Gardosa 6C
- Drift
- Grip
- Freeride
- Freestyle
- Cargo (RX)
- Ambient
- Cobra
- Everyday
- Cleanocean
- Kanjo Flex
- G-Tac
- F-Tac
- Net
- Tomcat
- Guardian
- Devil
- M-Cover (S)
- Nucleo 6C
- Life



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

- Mantra (RX)
- Solena (RX)
- Iconic 3.0
- Novena / S (RX)
- Nighthawk Sports (RX)
- M-Shield
- Glace
- View
- Nucleo
- Iconic 2.0 (RX)
- Secret (RX)
- Dawn
- Wire (RX)
- Gardosa Re+ / S (RX)
- Apache
- Attac
- Gardosa Evolution M/P
- Lanver
- Maverick
- Raptor
- Nighthawk
- Skyray
- Stingray M/P
- Blackhawk
- Signal (RX)
- Sprint (RX)

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

- Speedster (RX)
- C-Shield / S (RX)
- Outbreak / S
- Outbreak Evo / S
- Outbreak Luzzzone / S
- Defense

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EU-Konformitätserklärung/declaration  
of conformity

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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