



Name of manufacturer **Eschenbach Optik GmbH
Fürther Straße 252, 90429 Nürnberg
Germany**

Single Registration Number (SRN) **DE-MF-000007711**

We declare under sole responsibility that the product

Name of product **spectacle frames with sun protection / Models see Annex**

Basic UDI-DI **4064158FRA-MET-FULL001BR**

Nomenclature **GMDN Code 32816, EMDN Code Q02100201**

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

Risk category **Category I**

Conformity assessment procedure internal production control (module A) set out in annex IV

and conforms with the following regulations:

Regulation (EU) 2016/425 on personal protective equipment

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.

Nuremberg, 02.11.2021

Place and date of issue

sgd. M.Anke

**Name,
Matthias Anke**
Managing Director

sgd. A. Jahnke

**Name,
Andreas Jahnke**
MDR Responsible Person



Annex

| Model | Article | GTIN | Name |
|---------|-----------|---------------|-----------------------------|
| acunis | 1615325 | 4064158029524 | frame with acunis |
| acunis | 1615350 | 4064158029531 | frame with acunis |
| acunis | 1615375 | 4064158029548 | frame with acunis |
| acunis | 1615425 | 4064158029555 | frame with acunis |
| acunis | 1615450 | 4064158029562 | frame with acunis |
| acunis | 1615475 | 4064158029579 | frame with acunis |
| ambelis | 1666115 | 4048347120933 | frame with am filter lenses |
| ambelis | 166615015 | 4048347120940 | frame with am filter lenses |
| ambelis | 1666165 | 4048347120957 | frame with am filter lenses |
| ambelis | 1666175P | 4048347300052 | frame with am filter lenses |
| ambelis | 1666185 | 4048347193777 | frame with am filter lenses |
| ambelis | 1666215 | 4048347120902 | frame with am filter lenses |
| ambelis | 166625015 | 4048347120919 | frame with am filter lenses |
| ambelis | 1666265 | 4048347120926 | frame with am filter lenses |
| ambelis | 1666275P | 4048347300069 | frame with am filter lenses |
| ambelis | 1666285 | 4048347193784 | frame with am filter lenses |