



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, 23.10.2024

Place and date of issue

sgd. M.Anke

**Name,
Matthias Anke**
Managing Director

sgd. A. Jahnke

**Name,
Andreas Jahnke**
MDR Responsible Person



Annex

Model	Artikel	GTIN	Name
acunis	1615325	4064158029524	frame with ac filter lenses
acunis	1615350	4064158029531	frame with ac filter lenses
acunis	1615375	4064158029548	frame with ac filter lenses
acunis	1615425	4064158029555	frame with ac filter lenses
acunis	1615450	4064158029562	frame with ac filter lenses
acunis	1615475	4064158029579	frame with ac filter lenses
acunis	16156525	4064158290313	frame with ac filter lenses
acunis	16156550	4064158290320	frame with ac filter lenses
acunis	16156575	4064158290337	frame with ac filter lenses
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