



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 frame with sun protection / Models see Annex**

Basic UDI-DI **4064158FRA-PLA-FULL-0024U**

Nomenclature **GMDN Code 32816, EMDN Code Q02100202**

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	16156425	4064158029555	Frame with acunis
acunis	16156450	4064158029562	Frame with acunis
acunis	16156475	4064158029579	Frame with acunis
acunis	16618125	4064158063634	acunis XL
acunis	16618150	4064158063627	acunis XL
acunis	16618175	4064158063610	acunis XL
acunis	16619125	4064158063603	acunis XL
acunis	16619150	4064158063597	acunis XL
acunis	16619175	4064158063580	acunis XL
asensys	16618450	4048347708155	asensys XL
asensys	16618511	4048347708131	asensys XL
asensys	16618527	4048347708117	asensys XL
asensys	16618550	4048347708094	asensys XL
asensys	16619450	4048347708070	asensys XL
asensys	16619511	4048347708056	asensys XL
asensys	16619527	4048347708025	asensys XL
asensys	16619550	4048347708032	asensys XL
asensys	16618450P	4048347708162	asensys XL
asensys	16618511P	4048347708148	asensys XL
asensys	16618527P	4048347708124	asensys XL
asensys	16618550P	4048347708100	asensys XL
asensys	16619450P	4048347708087	asensys XL
asensys	16619511P	4048347708063	asensys XL
asensys	16619527P	4048347708018	asensys XL
asensys	16619550P	4048347708049	asensys XL
ambelis	1663115	4048347120933	frame with am filter lenses
ambelis	166315015	4048347120940	frame with am filter lenses
ambelis	1663165	4048347120957	frame with am filter lenses
ambelis	1663175P	4048347300052	frame with am filter lenses
ambelis	1663185	4048347193777	frame with am filter lenses
ambelis	1663215	4048347120902	frame with am filter lenses
ambelis	166325015	4048347120919	frame with am filter lenses
ambelis	1663265	4048347120926	frame with am filter lenses
ambelis	1663275P	4048347300069	frame with am filter lenses
ambelis	1663285	4048347193784	frame with am filter lenses
ambelis	1663415	4048347348054	frame with am filter lenses
ambelis	166341580	4048347474173	frame with am filter lenses



ambelis	166345015	4048347348023	frame with am filter lenses
ambelis	1663465	4048347348047	frame with am filter lenses
ambelis	1663475P	4048347348016	frame with am filter lenses
ambelis	1663485	4048347348030	frame with am filter lenses
ambelis	1663515	4048347347996	frame with am filter lenses
ambelis	166351580	4048347474180	frame with am filter lenses
ambelis	166355015	4048347347965	frame with am filter lenses
ambelis	1663565	4048347347989	frame with am filter lenses
ambelis	1663575P	4048347348061	frame with am filter lenses
ambelis	1663585	4048347347972	frame with am filter lenses
ambelis	1663815	4048347514282	fit-over frame with am filter lenses
ambelis	166381580	4048347515067	fit-over frame with am filter lenses
ambelis	166385015	4048347515241	fit-over frame with am filter lenses
ambelis	1663865	4048347514299	fit-over frame with am filter lenses
ambelis	1663875P	4048347514305	fit-over frame with am filter lenses
ambelis	1663885	4048347514312	fit-over frame with am filter lenses
ambelis	1663915	4048347514329	fit-over frame with am filter lenses
ambelis	166391580	4048347515050	fit-over frame with am filter lenses
ambelis	166395015	4048347515364	fit-over frame with am filter lenses
ambelis	1663965	4048347514336	fit-over frame with am filter lenses
ambelis	1663975P	4048347514343	fit-over frame with am filter lenses
ambelis	1663985	4048347514350	fit-over frame with am filter lenses
ambelis	1664115	4048347690313	frame with am filter lenses
ambelis	166415015	4048347690344	frame with am filter lenses
ambelis	1664165	4048347690320	frame with am filter lenses
ambelis	1664175P	4048347690351	frame with am filter lenses
ambelis	1664185	4048347690337	frame with am filter lenses
ambelis	1664215	4048347690368	frame with am filter lenses
ambelis	166425015	4048347690399	frame with am filter lenses
ambelis	1664265	4048347690375	frame with am filter lenses
ambelis	1664275P	4048347690405	frame with am filter lenses
ambelis	1664285	4048347690382	frame with am filter lenses
ambelis	1664415	4048347718178	frame with am filter lenses
ambelis	166445015	4048347718215	frame with am filter lenses
ambelis	1664465	4048347718185	frame with am filter lenses
ambelis	1664475P	4048347718192	frame with am filter lenses
ambelis	1664485	4048347718208	frame with am filter lenses
ambelis	1664515	4048347718222	frame with am filter lenses
ambelis	166455015	4048347718260	frame with am filter lenses



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ambelis	1664565	4048347718239	frame with am filter lenses
ambelis	1664575P	4048347718253	frame with am filter lenses
ambelis	1664585	4048347718246	frame with am filter lenses
ambelis	1664815	4048347707417	fit-over frame with am filter lenses
ambelis	166485015	4048347707493	fit-over frame with am filter lenses
ambelis	1664865	4048347707431	fit-over frame with am filter lenses
ambelis	1664875P	4048347707479	fit-over frame with am filter lenses
ambelis	1664885	4048347707455	fit-over frame with am filter lenses
ambelis	1664915	4048347707424	fit-over frame with am filter lenses
ambelis	166495015	4048347707509	fit-over frame with am filter lenses
ambelis	1664965	4048347707448	fit-over frame with am filter lenses
ambelis	1664975P	4048347707486	fit-over frame with am filter lenses
ambelis	1664985	4048347707462	fit-over frame with am filter lenses