



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 glasses with filter / filter variants see Annex**

Basic UDI-DI
**4064158L-150-SV-PHO-ORGKE
4064158L-150-SV-POL-ORGM8
4064158L-150-SV-OTH-ORGMC
4064158L-150-BF-PHO-ORGQE
4064158L-150-BF-POL-ORGS8
4064158L-150-BF-OTH-ORGSC
4064158L-150-VP-PHO-ORGHT
4064158L-150-VP-POL-ORGKM
4064158L-150-VP-OTH-ORGKR
4064158L-160-SV-PHO-ORGLP
4064158L-160-SV-POL-ORGNH
4064158L-160-SV-OTH-ORGNM
4064158L-160-BF-PHO-ORGRP
4064158L-160-BF-POL-ORGTH
4064158L-160-BF-OTH-ORGTM
4064158L-160-VP-PHO-ORGK4
4064158L-160-VP-POL-ORGLW
4064158L-160-VP-OTH-ORGM2**

Nomenclature
**GMDN Code 30048 tinted lens
EMDN Code Q0210010101
EMDN Code Q0210010102
EMDN Code Q0210010103**

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

Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Directive 94/62/EC on packaging and packaging waste

Document No.
2021_11_19_spectacle
glasses_all filter variants



EU Declaration of
conformity

 **ESCHENBACH**

Complies with European standards EN ISO 14889, EN ISO 21987, EN ISO 8980-1, EN ISO 8980-2,
EN ISO 8980-3, EN ISO 8980-4, EN ISO 8980-5

We operate a systematic procedure to monitor the product after placing it on the market.

Nuremberg, 19.11.2021

Place and date of issue

sgd. M. Anke

**Name,
Matthias Anke**
Managing Director

sgd. A. Jahnke

**Name,
Andreas Jahnke**
MDR Responsible Person



Annex

filter variants	Identification
ambelis 15	am 15
ambelis 65	am 65
ambelis 85	am 85
ambelis 75 Polarizing	am 75P
ambelis 50-15	am 50-15
ambelis active	am active
ambelis 15 Drive	am 15 D
ambelis 65 Drive	am 65 D
ambelis 85 Drive	am 85 D
ambelis 75 Polarizing Drive	am 75P D
ambelis 50-15 Drive	am 50-15 D
asensys 400	as 400
asensys 450	as 450
asensys 511	as 511
asensys 527	as 527
asensys 550	as 550
asensys 450 Polarizing	as 450 P
asensys 511 Polarizing	as 511 P
asensys 527 Polarizing	as 527 P
asensys 550 Polarizing	as 550 P
acunis 25	ac 25
acunis 50	ac 50
acunis 75	ac 75