



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 **ambelis spectacle frame / models see annex**

Basic UDI-DI **4064158FRA-MET-FULL001BR
4064158FRA-PLA-FULL-0024U**

Nomenclature **GMDN Code 32816
EMDN Code Q02100201, 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

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

Complies with European standard EN ISO 12870

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

Nuremberg, 26.05.2026
Place and date of issue

sgd. M. Anke
**Name,
Matthias Anke**
Managing Director

sgd. A. Jahnke
**Name,
Andreas Jahnke**
MDR Responsible Person



Annex

Model	Articel	GTIN	Name
ambelis	16635416	4048347121008	plastic spectacle frame, small unisex
ambelis Drive	16645416	4048347724964	plastic spectacle frame, small unisex
ambelis	16635716	4048347121015	plastic spectacle frame, small unisex
ambelis Drive	16645716	4048347724971	plastic spectacle frame, small unisex
ambelis	16635615	4048347348009	Women's plastic spectacle frame
ambelis Drive	16645415	4048347724995	Women's plastic spectacle frame
ambelis	16635816	4048347347958	Men's plastic spectacle frame
ambelis Drive	16645816	4048347724988	Men's plastic spectacle frame
ambelis	16665617	4048347766025	metal spectacle frame, small
ambelis	16665916	4048347766018	metal spectacle frame, large