EU Declaration of Conformity

in accordance with Regulation (EU) 2017/745 on Medical Devices[1]

[2]Manufacturer: Carl Zeiss Vision International GmbH, Turnstrasse 27, 73430 Aalen, Germany

[3](Single Registration Number: DE-MF-000006159)

We, ***Carl Zeiss Vision International GmbH*** with production sites listed in Annex 1 of this declaration herewith declare under our sole responsibility that the following medical device meets the requirements of the European Regulation (EU) 2017/745.[4]

Medical Device Name:	Spectacle lens, ZEISS branded and unbranded, monofocal (single vision), multifocal, variable focal (progressive), uncoated, hard coated and anti-reflective coated, tinted, polarized and photochromic, listed with product names and their UDI-DIs in Annex 3 of this declaration.[5]
Intended Use	Provide refractive correction or compensation of the eye, either fully or in part, in accordance with a prescription for the patient.[6]
[7]Medical Device Class **MDR 2017/745, Annex VIII**	Class 1 (non-sterile, non-measuring, non-reusable)
[8]Conformity Assessment Procedure	Annexes I, II, III of Regulation (EU) 2017/745
[9]Product Family Name/BASIC UDI-DI	In Annex 2 of this declaration
[10]The device is also in conformance with	EN ISO 14889, EN ISO 8980-1-2-3-4-5, EN ISO 21987, EN ISO 14971, EN ISO 10993-1, EN ISO 10993-18, ISO TR 20416, EN ISO 13485
[11]Reference to preceding certificate	Version 14 from 2025-03-31

This Declaration of Conformity is valid until 2027-01-01[12]
Any modification to the product not authorized by the manufacturer will invalidate this declaration.[13]

Sven Hermann,
President and CEO

Dr. Benjamin Viering
Member of the Board
COO & CTO

Aalen, 2025-06-23[14]