

EU-Konformitätserklärung

EU-Declaration of Conformity



Name und Adresse Hersteller / name and address of the manufacturer

NIKA Optics GmbH, Auf dem Meer 1, 56333 Winnigen – Germany

Diese Konformitätserklärung wird unter alleiniger Verantwortung des Herstellers ausgestellt. Dieser ist unter der SRN DE-MF-000012599 in EUDAMED registriert. Die zuständige Behörde ist DE/CA33 - Landesamt für Soziales, Jugend und Versorgung, Dienststelle Mainz.

This declaration of conformity is issued under the sole responsibility of the manufacturer. The manufacturer is registered under SRN DE-MF-000012599 in EUDAMED. The responsible authority is DE/CA33 - Landesamt für Soziales, Jugend und Versorgung, Dienststelle Mainz.

Gegenstand der Erklärung: Medizinprodukt der Klasse 1 – Brillenglas nach Anhang VIII, Regel 1, der Verordnung (EU) 2017/745 (MDR).

Subject of the declaration: medical devices class 1 – spectacle lens, according to annex VIII, rule 1 of regulation (EU) 2017/745.

Das oben genannte Medizinprodukt ist konform mit der Verordnung (EU) 2017/745 über Medizinprodukte und erfüllt die anwendbaren Produktnormen:

The medical device mentioned above is compliant with Regulation (EU) 2017/745 on medical devices and meets the applicable product standards:

DIN EN ISO 8980-1:2017-12

DIN EN ISO 14889:2018-04

DIN EN ISO 8980-2:2017-12

DIN EN ISO 21987:2017-12

DIN EN ISO 8980-3:2014-03

DIN EN ISO 13485:2016-08

DIN EN ISO 8980-4:2006-11

DIN EN ISO 14971:2020-07

DIN EN ISO 8980-5:2005-05

MEDDEV 2.7/1 rev4:2016-06

Diese Erklärung ist nur gültig für das oben angegebene Medizinprodukt.

This declaration is only valid for the medical device indicated above.

Konformitätsbewertungsverfahren / conformity assessment procedure

Diese EU-Konformitätserklärung wird ausgestellt, nachdem die technische Dokumentation gemäß den Anhängen II und III der Verordnung (EU) 2017/745 erstellt wurde.

This EU-Declaration of Conformity is issued after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745.

Winnigen den, 01.04.2022

A handwritten signature in black ink, appearing to read "R. Thiehofe".

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Ort und Datum der Ausstellung

NIKA Optics GmbH Ralf Thiehofe, Geschäftsführer

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Anhang:

Folgende Produkte unterliegen der aktuell gültigen EU-Konformitätserklärung:

Following products are liable to the currently valid EU declaration of conformity:

Alle Produkte, die in den jeweils aktuellen NIKA Produkt- und Preislisten aufgeführt sind.

All products that are listed in the current NIKA product and price lists.

Basic UDI-DI Brillengläser (spectacle lenses)

Basic UDI-DI	Design	Lens material	index	Options
42518117SV-or-1.5-othV3	Single Vision	organic	1,5	others (clear, tinted)
42518117SV-or-1.5-phoUJ	Single Vision	organic	1,5	photochromic
42518117SV-or-1.5-polUZ	Single Vision	organic	1,5	polarized
42518117SV-or-1.53-othNK	Single Vision	organic	1,53	others (clear, tinted)
42518117SV-or-1.53-phoN2	Single Vision	organic	1,53	photochromic
42518117SV-or-1.59-othQM	Single Vision	organic	1,59	others (clear, tinted)
42518117SV-or-1.59-phoQ4	Single Vision	organic	1,59	photochromic
42518117SV-or-1.59-polQK	Single Vision	organic	1,59	polarized
42518117SV-or-1.6-othVE	Single Vision	organic	1,6	others (clear, tinted)
42518117SV-or-1.6-phoUV	Single Vision	organic	1,6	photochromic
42518117SV-or-1.6-polVC	Single Vision	organic	1,6	polarized
42518117SV-or-1.67-othQC	Single Vision	organic	1,67	others (clear, tinted)
42518117SV-or-1.67-phoPT	Single Vision	organic	1,67	photochromic
42518117SV-or-1.67-polQA	Single Vision	organic	1,67	polarized
42518117SV-or-1.74-othPQ	Single Vision	organic	1,74	others (clear, tinted)
42518117SV-or-1.74-phoP7	Single Vision	organic	1,74	photochromic
42518117SV-min-1.5-othL2	Single Vision	mineral	1,5	others (clear, tinted)
42518117SV-min-1.5-phoKH	Single Vision	mineral	1,5	photochromic
42518117SV-min-1.6-othLD	Single Vision	mineral	1,6	others (clear, tinted)
42518117SV-min-1.6-phoKU	Single Vision	mineral	1,6	photochromic
42518117SV-min-1.7-othLQ	Single Vision	mineral	1,7	others (clear, tinted)
42518117SV-min-1.8-othM3	Single Vision	mineral	1,8	others (clear, tinted)
42518117SV-min-1.9-othME	Single Vision	mineral	1,9	others (clear, tinted)
42518117BM-or-1.5-othUS	Bifocal / Multifocal	organic	1,5	others (clear, tinted)
42518117BM-or-1.5-phoU9	Bifocal / Multifocal	organic	1,5	photochromic
42518117BM-or-1.6-othV5	Bifocal / Multifocal	organic	1,6	others (clear, tinted)
42518117BM-or-1.6-phoUL	Bifocal / Multifocal	organic	1,6	photochromic
42518117BM-or-1.67-othMV	Bifocal / Multifocal	organic	1,67	others (clear, tinted)
42518117BM-or-1.67-phoMC	Bifocal / Multifocal	organic	1,67	photochromic
42518117BM-or-1.74-othM9	Bifocal / Multifocal	organic	1,74	others (clear, tinted)

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Basic UDI-DI	Design	Lens material	index	Options
42518117BM-or-1.74-phoLQ	Bifocal / Multifocal	organic	1,74	photochromic
42518117BM-min-1.5-othHK	Bifocal / Multifocal	mineral	1,5	others (clear, tinted)
42518117BM-min-1.5-phoH2	Bifocal / Multifocal	mineral	1,5	photochromic
42518117BM-min-1.6-othHW	Bifocal / Multifocal	mineral	1,6	others (clear, tinted)
42518117PV-or-1.5-othR8	Power Variation	organic	1,5	others (clear, tinted)
42518117PV-or-1.5-phoQP	Power Variation	organic	1,5	photochromic
42518117PV-or-1.5-polR6	Power Variation	organic	1,5	polarized
42518117PV-or-1.53-othJJ	Power Variation	organic	1,53	others (clear, tinted)
42518117PV-or-1.53-phoHZ	Power Variation	organic	1,53	photochromic
42518117PV-or-1.59-othLL	Power Variation	organic	1,59	others (clear, tinted)
42518117PV-or-1.59-phoL3	Power Variation	organic	1,59	photochromic
42518117PV-or-1.59-polJJ	Power Variation	organic	1,59	polarized
42518117PV-or-1.6-othRK	Power Variation	organic	1,6	others (clear, tinted)
42518117PV-or-1.6-phoR2	Power Variation	organic	1,6	photochromic
42518117PV-or-1.6-polRH	Power Variation	organic	1,6	polarized
42518117PV-or-1.67-othLB	Power Variation	organic	1,67	others (clear, tinted)
42518117PV-or-1.67-phoKS	Power Variation	organic	1,67	photochromic
42518117PV-or-1.67-poll9	Power Variation	organic	1,67	polarized
42518117PV-or-1.74-othKP	Power Variation	organic	1,74	others (clear, tinted)
42518117PV-or-1.74-phoK6	Power Variation	organic	1,74	photochromic
42518117PV-min-1.5-othFZ	Power Variation	mineral	1,5	others (clear, tinted)
42518117PV-min-1.5-phoFG	Power Variation	mineral	1,5	photochromic
42518117PV-min-1.6-othGC	Power Variation	mineral	1,6	others (clear, tinted)
42518117PV-min-1.6-phoFT	Power Variation	mineral	1,6	photochromic
42518117PV-min-1.7-othGP	Power Variation	mineral	1,7	others (clear, tinted)
42518117PV-min-1.8-othH2	Power Variation	mineral	1,8	others (clear, tinted)
42518117PV-min-1.9-othHD	Power Variation	mineral	1,9	others (clear, tinted)