



**Declarație de conformitate**  
**Declaration of conformity**

Nume fabricant / *Name of manufacturer*

**INTEROPTIK S.R.L.**

Sediul Social / *Registered Office*

**str. S.M. Caceu 39, Timișoara 300568, România**

SRN Număr Unic de Înregistrare /  
*SRN Single Registration Number*

**RO – MF – 000016269**

Noi, **INTEROPTIK S.R.L.** declarăm pe propria răspundere că dispozitivele medicale **Lentile Unifocale, Lentile cu Putere Variabilă și Lentile Bifocale** sunt dispozitive medicale **clasa I** (nesterile, fără funcție de măsurare și nerefolosibile), îndeplinesc cerințele esențiale aplicabile ale Regulamentului UE 2017 / 745 și sunt conforme cu documentația tehnică.

*We, **INTEROPTIK S.R.L.** declare under sole responsibility that the medical devices **Single Vision Lenses, Variation Power Lenses and Bifocal Lenses** are **class 1** medical devices (non-sterile, non-measuring non-reusable), comply with the essential applicable requirements of EU Regulation 2017 / 745 and they comply with the technical documentation.*

Utilizarea prevăzută:  
*Intendend use:*

**Corectarea refracției ochiului**  
**Refractive correction of the eye**

Identificarea produsului prin:

**Nume produs pe plicul lentilei**  
**UDI-DI de bază (în Anexa 1)**  
**Name of product on lens envelope**  
**Basic UDI-DI (in Annex 1)**

*Product Identification by:*

Procedura de evaluare a conformității  
*Conformity assessment procedure*

**Anexa II și III din Regulamentul UE 2017 / 745**  
**Annex II and III of EU Regulation 2017 / 745**

Reguli de clasificare:

**Anexa VIII, capitolul III, punctul 4 dispozitive neinvazive regula 1, din Regulamentul UE 2017/745**  
**Annex VIII, chapter III, point 4 non-invasive devices rule 1, of EU Regulation 2017 / 745**

*Classification rules:*

Standarde aplicate  
*Applied Standards*

**EN ISO 14889: 2015 + A1: 2017**  
**EN ISO 8980-1: 2018;-2: 2018;-3: 2014;-4: 2007;**  
**EN ISO 15223-1: 2021; EN ISO 13485: 2016**

Locul și data emiterii /  
*Place and date of issue.*

**Timișoara, 14.02.2022**

Persoana Responsabilă Conformitate /  
*Person Responsible for Regulatory Compliance.*

Director General Adjunct  
*Deputy General Manager*

**Lădariu Lucian Ionuț**



**Declarație de conformitate**  
**Declaration of conformity**

**Anexa 1: UDI-DI de bază corespunzător fiecărei familii de produse**  
**Annex 1: Basic UDI-DI for each product families**

**Lentile Unifocale**  
**Single Vision Lenses**

<b>Nume Produs</b> <b>Product name</b>	<b>Familia de produse</b> <b>Product Family</b>	<b>UDI-DI de bază:</b> <b>Basic UDI-DI:</b>
Optim	Single Vision Organic Clear 1.50	5944759052SV-ORG-CLR150R5
Aveo	Single Vision Organic Polarized 1.50	5944759052SV-ORG-POL150W5
Avantaj	Single Vision Organic Photochromic 1.50	5944759052SV-ORG-PHO150UD
Eurolens	Single Vision Organic Clear 1.53	5944759052SV-ORG-CLR153RB
	Single Vision Organic Polarized 1.53	5944759052SV-ORG-POL153WB
	Single Vision Organic Photochromic 1.53	5944759052SV-ORG-PHO153UK
	Single Vision Organic Photochromic 1.54	5944759052SV-ORG-PHO154UM
	Single Vision Organic Clear 1.56	5944759052SV-ORG-CLR156RH
	Single Vision Organic Photochromic 1.56	5944759052SV-ORG-PHO156UR
	Single Vision Organic Clear 1.59	5944759052SV-ORG-CLR159RP
	Single Vision Organic Clear 1.60	5944759052SV-ORG-CLR160R8
	Single Vision Organic Polarized 1.60	5944759052SV-ORG-POL160W8
	Single Vision Organic Photochromic 1.60	5944759052SV-ORG-PHO160UG
	Single Vision Organic Clear 1.67	5944759052SV-ORG-CLR167RN
	Single Vision Organic Polarized 1.67	5944759052SV-ORG-POL167WN
	Single Vision Organic Photochromic 1.67	5944759052SV-ORG-PHO167UW
	Single Vision Organic Clear 1.74	5944759052SV-ORG-CLR174RK
	Single Vision Organic Photochromic 1.74	5944759052SV-ORG-PHO174UT
	Single Vision Mineral Clear 1.50	5944759052SV-MIN-CLR150LZ
	Single Vision Mineral Photochromic 1.50	5944759052SV-MIN-PHO150Q9
	Single Vision Mineral Clear 1.60	5944759052SV-MIN-CLR160M4
	Single Vision Mineral Photochromic 1.60	5944759052SV-MIN-PHO160QC
	Single Vision Mineral Clear 1.70	5944759052SV-MIN-CLR170M7
Single Vision Mineral Clear 1.80	5944759052SV-MIN-CLR180MA	
Single Vision Mineral Clear 1.90	5944759052SV-MIN-CLR190MD	

Numele produselor se corelează cu UDI-DI de bază, în funcție de versiune (material, design, opțiuni, index) /  
Product names correlate with basic UDI-DI depending on the version (material, design, options, index).



**Declarație de conformitate**  
**Declaration of conformity**

**Anexa 1: UDI-DI de bază corespunzător fiecărei familii de produse**  
**Annex 1: Basic UDI-DI for each product families**

**Lentile cu Putere Variabilă**  
**Variation Power Lenses**

<b>Nume Produs</b> <b>Product name</b>	<b>Familia de produse</b> <b>Product Family</b>	<b>UDI-DI de bază:</b> <b>Basic UDI-DI:</b>
Excelit	Variable Power Organic Clear 1.50	5944759052VP-ORG-CLR150N2
Progresiv Aveo	Variable Power Organic Polarized 1.50	5944759052VP-ORG-POL150T2
Progresiv Avantaj	Variable Power Organic Photochromic 1.50	5944759052VP-ORG-PHO150RA
Office	Variable Power Organic Clear 1.53	5944759052VP-ORG-CLR153N8
Degresiv Aveo	Variable Power Organic Polarized 1.53	5944759052VP-ORG-POL153T8
Degresiv Avantaj	Variable Power Organic Photochromic 1.53	5944759052VP-ORG-PHO153RG
	Variable Power Organic Photochromic 1.54	5944759052VP-ORG-PHO154RJ
	Variable Power Organic Clear 1.56	5944759052VP-ORG-CLR156NE
	Variable Power Organic Photochromic 1.56	5944759052VP-ORG-PHO156RN
	Variable Power Organic Clear 1.60	5944759052VP-ORG-CLR160N5
	Variable Power Organic Polarized 1.60	5944759052VP-ORG-POL160T5
	Variable Power Organic Photochromic 1.60	5944759052VP-ORG-PHO160RD
	Variable Power Organic Clear 1.67	5944759052VP-ORG-CLR167NK
	Variable Power Organic Polarized 1.67	5944759052VP-ORG-POL167TK
	Variable Power Organic Photochromic 1.67	5944759052VP-ORG-PHO167RT
	Variable Power Organic Clear 1.74	5944759052VP-ORG-CLR174NG
	Variable Power Organic Photochromic 1.74	5944759052VP-ORG-PHO174RQ
	Variable Power Mineral Clear 1.50	5944759052VP-MIN-CLR150HW
	Variable Power Mineral Photochromic 1.50	5944759052VP-MIN-PHO150M6
	Variable Power Mineral Clear 1.60	5944759052VP-MIN-CLR160HZ
	Variable Power Mineral Photochromic 1.60	5944759052VP-MIN-PHO160M9
	Variable Power Mineral Clear 1.70	5944759052VP-MIN-CLR170J4
	Variable Power Mineral Clear 1.80	5944759052VP-MIN-CLR180J7

Numele produselor se corelează cu UDI-DI de bază, în funcție de versiune (material, design, opțiuni, index) /  
Product names correlate with basic UDI-DI depending on the version (material, design, options, index).



**Declarație de conformitate**  
***Declaration of conformity***

**Anexa 1: UDI-DI de bază corespunzător fiecărei familii de produse**  
***Annex 1: Basic UDI-DI for each product families***

**Lentile Bifocale**  
***Bifocal Lenses***

<b>Nume Produs</b> <b><i>Product name</i></b>	<b>Familia de produse</b> <b><i>Product Family</i></b>	<b>UDI-DI de bază:</b> <b><i>Basic UDI-DI:</i></b>
Bifocal Optim	Bifocal Organic Clear 1.50	5944759052BF-ORG-CLR150GR
Bifocal Aveo	Bifocal Organic Photochromic 1.50	5944759052BF-ORG-PHO150KZ
Bifocal Avantaj	Bifocal Organic Photochromic 1.53	5944759052BF-ORG-PHO153L7
Bifocal Mineral	Bifocal Organic Photochromic 1.54	5944759052BF-ORG-PHO154L9
	Bifocal Organic Photochromic 1.56	5944759052BF-ORG-PHO156LD
	Bifocal Organic Clear 1.60	5944759052BF-ORG-CLR160GU
	Bifocal Organic Photochromic 1.60	5944759052BF-ORG-PHO160L4
	Bifocal Organic Clear 1.67	5944759052BF-ORG-CLR167HA
	Bifocal Mineral Clear 1.50	5944759052BF-MIN-CLR150CM
	Bifocal Mineral Photochromic 1.50	5944759052BF-MIN-PHO150FV

Numele produselor se corelează cu UDI-DI de bază, în funcție de versiune (material, design, opțiuni, index) /  
*Product names correlate with basic UDI-DI depending on the version (material, design, options, index).*