



INSTRUCTIUNI DE UTILIZARE INSTRUCTIONS FOR USE

Brand: SIFRA Producator / Manufacturer: MERCAN OPTIK ITHALAT IHRACAT SAN.
VE TIC. LTD. STI.

Clasa / Class: I (MDR 2017/745) GMDN: 32816 Ref: ISO 12870

■■ ROMANA

■■ ENGLISH

1. DOMENIU DE UTILIZARE

Ramele de ochelari de vedere SIFRA sunt dispozitive medicale Clasa I (Regula 1, Capitolul III, Anexa VIII din Regulamentul (UE) 745/2017).

Acestea sunt destinate exclusiv utilizarii impreuna cu lentilele oftalmice de corectie, in scopul sustinerii protezelor oculare si al corectarii defectelor de vedere.

Produsul este conform cu Regulamentul (UE) 2017/745 privind dispozitivele medicale si cu standardul EN ISO 12870 (rame de ochelari oftalmici — cerinte si metode de incercare).

Nu este destinat utilizarii ca ochelari de soare, ochelari de protectie sau oricarui alt scop nemedicinal.

2. AVERTIZARI

Rama este livrata cu lentile de prezentare, care nu sunt destinate utilizarii si au doar rolul de a mentine forma si de a permite probarea in conditii cat mai reale.

Acesta nu este un echipament de protectie — a nu se utiliza ca atare.

A nu se lasa la indemana copiilor.

In caz de deteriorare vizibila (fisuri, deformari), nu mai utilizati produsul si adresati-va unui optician autorizat.

3. CURATARE SI INTRETINERE

Pastrati ramele la o temperatura ce nu depaseste 90°C, in tocul furnizat.

Evitati expunerea prelungita la soare in spatii inchise (ex. bordul masinii).

In caz de contact cu apa sarata, apa de piscina, produse cosmetice sau fixativ, stergeti imediat cu o carpa moale umeda.

Folositi exclusiv produse recomandate de opticianul dvs.: laveta microfibra, solutii cu pH neutru sau servetele speciale pentru ochelari.

Evitati solventii (acetona, alcool) si detergentii chimici care pot deteriora materialele ramei.

In caz de uzura (zgarieturi, pete), inlocuiti componentele doar cu produse originale, in centre optice autorizate.

4. MARCAJ CE

Marcajul CE aplicat pe produs atesta conformitatea cu cerintele esentiale ale Regulamentului (UE) 2017/745 privind dispozitivele medicale.

Codul de identificare al modelului si dimensiunile produsului se gasesc pe partea interioara a bratelor.

Codul UDI-DI de baza: 8680277BXPLSGC01XZ / 8680277BXMTLGC01X9 / 8680277BXMIXGC01WW

5. PRODUCATOR

MERCAN OPTIK ITHALAT IHRACAT SAN. VE TIC. LTD. STI.

Ikiteilli O.S.B. Mutsan Sitesi M4 Blok No:10

Basaksehir — Istanbul / Turcia

SRN: TR-MF-000052576

6. SESIZARI SI RECLAMATII

Importator in Romania: Sifra Vision SRL

Str. G-ral Alexandru Cernat nr. 188, Galati, Romania

E-mail: office@sifravision.ro | Web: www.sifravision.ro

Orice incident grav legat de utilizarea acestui dispozitiv medical trebuie raportat autoritatii competente nationale (ANMDMR).

1. INTENDED USE

SIFRA spectacle frames are Class I medical devices (Rule 1, Chapter III, Annex VIII of Regulation (EU) 745/2017).

They are intended exclusively for use with prescription ophthalmic lenses, to support ocular prostheses and correct visual defects.

The product complies with Regulation (EU) 2017/745 on medical devices and with standard EN ISO 12870 (ophthalmic frames — requirements and test methods).

Not intended for use as sunglasses, protective eyewear, or any other non-medical purpose.

2. WARNINGS

The frame is delivered with demonstration lenses, which are not intended for use and serve only to maintain the shape and allow fitting under realistic conditions.

This is not personal protective equipment — do not use it as such.

Keep out of reach of children.

If visible damage is present (cracks, deformation), discontinue use and consult an authorised optician.

3. CLEANING AND MAINTENANCE

Store the frames at a temperature not exceeding 90°C, in the provided case.

Avoid prolonged exposure to sunlight in enclosed spaces (e.g. car dashboard).

If in contact with salt water, pool water, cosmetics or hairspray, wipe immediately with a soft damp cloth.

Use only products recommended by your optician: microfibre cloth, pH-neutral solutions or special lens cleaning wipes.

Avoid solvents (acetone, alcohol) and chemical detergents that may damage the frame materials.

In case of wear (scratches, stains), replace components only with original parts, at authorised optical centres.

4. CE MARKING

The CE marking affixed to the product certifies compliance with the essential requirements of Regulation (EU) 2017/745 on medical devices.

The model identification code and product dimensions are found on the inner side of the temples.

Basic UDI-DI: 8680277BXPLSGC01XZ / 8680277BXMTLGC01X9 / 8680277BXMIXGC01WW

5. MANUFACTURER

MERCAN OPTIK ITHALAT IHRACAT SAN. VE TIC. LTD. STI.

Ikiteilli O.S.B. Mutsan Sitesi M4 Blok No:10

Basaksehir — Istanbul / Turkey

SRN: TR-MF-000052576

6. COMPLAINTS AND REPORTS

Romanian importer: Sifra Vision SRL

Str. G-ral Alexandru Cernat nr. 188, Galati, Romania

E-mail: office@sifravision.ro | Web: www.sifravision.ro

Any serious incident related to the use of this medical device must be reported to the national competent authority (ANMDMR).