

(IT) Istruzione per l'uso **SISTEMA INGRADENTE:**  
-OCCHIALE BINOCULARE TTL  
-OCCHIALE BINOCULARE FLIP UP  
-CASCHETTO BINOCULARE FLIP UP

Grazie per la fiducia accordataci e complimenti per la scelta.  
Prima di utilizzare il dispositivo, leggere la seguente nota informativa.

#### DESCRIZIONE DELLE COMPONENTI

La guida all'uso del sistema ingradente, l'elenco delle componenti e delle parti di ricambio sono riportate nella documentazione resa disponibile con il dispositivo.

#### SIMBOLI

☉ In conformità al Regolamento (UE) 2017/745 in materia di dispositivi medici

🏭 Data di fabbricazione    🏭 Fabbricante    📖 REF Numero di catalogo

📄 SN Seriale    🏷️ LOT Numero di lotto    📖 Istruzioni d'uso    ⚠️ Attenzione

**DESTINAZIONE D'USO**  
Il dispositivo è destinato a migliorare l'acuità visiva in un range ristretto del campo visivo in ambiti di applicazione medica e destinato alla compensazione di un deficit visivo quando dotato di lenti portanti oftalmiche.  
Utilizzatori previsti: professionisti in campo medico.  
Pazienti previsti: nessuna limitazione ad eccezione di quanto espresso nella sezione "controindicazioni" se presente.

**DISPOSITIVI UTILIZZABILI CONGIUNTAMENTE**  
Il dispositivo può essere utilizzato in abbinamento a tutti i modelli di sistemi di illuminazione Univet, formando un sistema integrato di visione.

TIPOLOGIA SISTEMA INGRADENTE	TIPOLOGIA SISTEMA OTTICO	INGRANDIMENTO	DISTANZA DI LAVORO [mm]
OCCHIALE BINOCULARE TTL	GALILEIANO	2.0X PRO HD	300
		2.5X PRO HD	350
		3.0X PRO HD	400
		3.5X PRO HD	450
	PRISMATICO	3.5X XS ULTRA-HD	300
		4.0X XS ULTRA-HD	350
OCCHIALE BINOCULARE FLIP UP	GALILEIANO	2.5X PRO HD	300
			350
			400
	PRISMATICO	3.5X ULTRA-HD	300
		4.5X ULTRA-HD	350
			400
			450
		6.0X ULTRA-HD	500
CASCHETTO BINOCULARE FLIP UP	PRISMATICO	3.5X ULTRA-HD	300
		4.5X ULTRA-HD	350
			400
	PRISMATICO	4.5X ULTRA-HD	400
			450
		6.0X ULTRA-HD	500

**CONTROINDICAZIONI**  
Il dispositivo (occhiale dotato di sistema ingradente TTL) è controindicato nel caso di utilizzatori affetti da strabismo.

K600028.00\_Rev.00\_24.02.2021



(EN) Instructions for use - **MAGNIFYING SYSTEM:**  
-TTL BINOCULAR LOUPES  
-FLIP UP BINOCULAR LOUPES  
-FLIP UP BINOCULAR HEADGEAR

Thank you for your trust in us and congratulations on your choice.  
Read the following information before using the device.

**DESCRIPTION OF THE COMPONENTS**  
The user guide for the magnifying system, the list of components and spare parts are indicated in the documents provided along with the device.

**SYMBOLS**  
☉ In compliance with Regulation 2017/745 on medical devices

🏭 Date of manufacture    🏭 Manufacturer    📖 REF Catalogue number

📄 SN Serial number    🏷️ LOT Batch number    📖 Instructions for use    ⚠️ Caution

**INTENDED USE**  
The device is intended to improve visual acuity in a narrow range of the visual field in medical applications and intended to compensate for a visual defect when equipped with ophthalmic load-bearing lenses.  
Intended users: medical professionals.  
Intended patients: no limitation except as stated in the "contraindications" section.

**DEVICES THAT CAN BE USED TOGETHER**  
The device can be comfortably attached to all Univet Lighting system models, thus providing an integrated vision system.

TYPE OF MAGNIFYING SYSTEM	TYPE OF OPTICAL SYSTEM	MAGNIFICATION	WORKING DISTANCE [mm]
TTL BINOCULAR LOUPES	GALILEAN	2.0X PRO HD	300
		2.5X PRO HD	350
		3.0X PRO HD	400
		3.5X PRO HD	450
	PRISMATIC	3.5X XS ULTRA-HD	300
	4.0X XS ULTRA-HD	350	
FLIP UP BINOCULAR LOUPES	GALILEAN	2.5X PRO HD	300
			350
			400
FLIP UP BINOCULAR HEADGEAR	PRISMATIC	3.5X ULTRA-HD	300
		4.5X ULTRA-HD	350
		6.0X ULTRA-HD	400
	PRISMATIC	4.5X ULTRA-HD	400
		6.0X ULTRA-HD	400

**CONTRAINDICATIONS**  
The device (loupes equipped with TTL magnifying system) is not recommended for users suffering from strabismus.  
FLIP UP magnifying systems are recommended for operators suffering from strabismus when



used along with the corrective spectacles thereof in use.  
The device is contraindicated in the event of applications requiring image stability that cannot be achieved with devices mounted on the user's head.

**WARNINGS**  
⚠️ Read the following warnings carefully before using the device.

Make sure that it is suitable for the intended use.  
Clean the device before use.  
Do not use the device if it has been damaged but contact your authorised dealer.  
Use the supplied components only.  
Ensure that the shields (if provided) are correctly fitted, otherwise stop the procedure in progress.  
Do not tamper with or disassemble any component of the system.  
Do not attempt any repairs.  
In the event of a malfunction, stop using the device, contact your authorised dealer.  
When not in use, store the device in its container.

**PRECAUTIONS**  
For any component adjustment and fitting instructions when using for the first time, please see the information provided by the manufacturer.  
Avoid contact with heat and cold sources or open flames.  
To avoid damaging the eyes, please do not look directly into light sources.  
Avoid sudden movements with your head when using the device.  
Avoid walking with the device worn.  
Do not wear the device over headgear.  
Please use the elastic band when using loupes equipped with TTL and FLIP UP magnifying system.

**ADVERSE EFFECTS**  
No adverse effects detected  
**SUPPLY MODE**  
This device is not supplied sterile. This is not a single use device.  
**STORAGE AND/OR HANDLING**  
Store the device at the temperatures and humidity indicated in the "Technical Specifications" section.  
When not in use, store the cleaned device in its original packaging.  
Handle the device strictly by holding by the temples (in the case of Loupes) or by the bands (in the case of Headgears).

**MAINTENANCE**  
Routine maintenance consists of cleaning the device as described in the "cleaning instructions" section.  
Ensure that the components of the device are fitted and adjusted correctly before use.  
Keep the original packaging required for return/maintenance shipment and contact your authorised dealer, see the instructions laid down by the warranty.

**TRAINING AND QUALIFICATIONS FOR USE**  
None.  
**CLEANING INSTRUCTIONS**  
Use a microfibre cloth to clean the lenses.  
All the other surfaces can be cleaned with a soft cloth soaked with a gentle detergent solution. This device cannot be sterilised. Do not clean in an ultrasonic bath.  
**DISPOSAL INSTRUCTIONS**  
The device does not contain toxic or hazardous materials. Disinfect the device before disposal.  
In the event of disposal/demolishing, do not dispose of the device in the environment, comply with the relevant national regulations.

**HEALTH RISKS**  
No health risk detected.  
**WARRANTY**  
See the instructions laid down by the warranty.  
Report any serious accidents involving the device to the manufacturer and the competent authority of the Member state in which the user and/or the patient resides.

**TECHNICAL SPECIFICATIONS**  
**Operating conditions**  
Room temperature.....from +10°C to +40°C  
Relative humidity.....from 10% to 90%  
**Storage and transportation conditions**  
Room temperature.....from -10°C to + 50°C  
Relative humidity.....from 10% to 90%  
Store in a dry place away from heat and cold

**CLINICAL BENEFITS**  
Given that it offers greater visual acuity (magnification) and facilitates a smaller angle of the position of the operator's neck, the device helps the user to maintain the correct posture during use, hence avoiding the onset of musculoskeletal problems.  
No adverse effects for the user.  
Univet's magnifying systems are effective and safe when used as intended.

For languages not included in these use instructions, please see the following link: [www.univetloupes.com/instructions](http://www.univetloupes.com/instructions)

🏭 Univet Loupes Spa – Via G.Prati 87, 25086, Rezzato (BS) Italy  
[www.univetloupes.com](http://www.univetloupes.com)

(FR) Mode d'emploi - **SYSTÈME GROSSISSANT:**  
-LOUPES BINOCULAIRES TTL  
-LOUPES BINOCULAIRES FLIP UP  
-CASQUE BINOCULAIRES FLIP UP

Nous vous remercions de la confiance que vous nous avez accordée et vous félicitons de votre choix.  
Avant d'utiliser le dispositif, veuillez lire la note d'information suivante.

#### DESCRIPTION DES COMPOSANTS

Le guide d'emploi du système grossissant, la liste des composants et des pièces détachées figurent dans la documentation fournie avec le dispositif.

**SYMBOLES**  
☉ Selon le règlement 2017/745/UE en matière de dispositifs médicaux

🏭 Date de fabrication    🏭 Fabricant    📖 REF Numéro de catalogue

📄 SN Numéro de série    🏷️ LOT Numéro de lot    📖 Mode d'emploi    ⚠️ Attention

**USAGE**  
Le dispositif est destiné à améliorer l'acuité visuelle dans une zone réduite du champ visuel dans le domaine d'application médical et destiné à compenser un défaut visuel lorsqu'il est muni de verres porteurs ophtalmiques.  
Utilisateurs prévus: professionnels dans le domaine médical.  
Patients prévus: aucune limitation, excepté ce qui est indiqué dans la rubrique "contre-indications".

**DISPOSITIFS UTILISABLES CONJOINTEMENT**  
Le dispositif peut facilement être fixé à tous les modèles de système d'éclairage Univet, permettant ainsi un système de vision intégré.

TYPE DE SYSTÈME GROSSISSANT	TYPE DE SYSTÈME OPTIQUE	GROSSISSEMENT	DISTANCE DE TRAVAIL [mm]
LOUPES BINOCULAIRES TTL	GALILÉE	2.0X PRO HD	300
		2.5X PRO HD	350
		3.0X PRO HD	400
		3.5X PRO HD	450
	PRISMATIQUE	3.5X XS ULTRA-HD	300
	4.0X XS ULTRA-HD	350	
LOUPES BINOCULAIRES FLIP UP	PRISMATIQUE	4.0X XS ULTRA-HD	400
		5.0X XS ULTRA-HD	450
		6.0X ULTRA-HD	500
CASQUE BINOCULAIRE FLIP UP	GALILÉE	2.5X PRO HD	300
			350
			400
	PRISMATIQUE	3.5X ULTRA-HD	300
		4.5X ULTRA-HD	350
		6.0X ULTRA-HD	400

**CONTRE-INDICATIONS**  
Le dispositif (loupes munies de système grossissant TTL) est contre-indiqué en cas d'utilisateurs atteints de strabisme.



