

USER MANUAL

eye mask



E-SWIN

www.e-swin.com

eye mask USER MANUAL

This document is accompanied with the eye mask according to requirements of the Regulation (EU) 2016/425 published in the Official Journal of the European Union on 9 March 2016.

I. PRECAUTIONS FOR USE

1. Intended use of the eye mask:

This eye mask is intended to be used in clinical medical environments to protect the eyes of patients from hazardous laser radiation during the eye treatment. It is not required for the patient to be able to see anything or must be oriented around a working place. Complete protection of the eyes is given by a completely opaque eye cup.

This eye mask is not intended to be used for directly looking to laser radiation beam. This product is only used for protection of the eyes of patients from accidental exposure to laser radiation during the eye treatment.

This eye mask does not protect from any mechanical impact.

2. For your safety:

Before using your eye mask, the following information should be read carefully:

- The eye mask can basically be used at all times by persons under treatment so as to protect their eyes from laser radiation from the environment onto the eyepiece.
- The eye mask is made of a completely opaque material and shall only be used to protect the eyes from hazardous laser radiation during the eye treatment.
- The eye mask must not be used if it is damaged, broken, distorted, has scratched oculars, or has undergone a color change.
- Patient who is wearing glasses must remove the glasses before wearing the eye mask.
- Clean the eye mask before each use according to practitioner's instructions.
- Put the eye mask in the right direction (e.g. the below pictures):



- Put the eye mask in the correct position where the eyes are covered fully by the opaque eye cups, then fasten the white cord by the black snap joint:



- Patient should close his/her eyes while wearing the eye mask during the treatment.
- Never use wet hand to touch to the goggles of the eye mask.
- Disinfect the eye mask after each session according to practitioner's instructions.

3. Attention

This eye mask is recommended to be used as one of the supplement accessories for E-SWIN products only.

E-SWIN can't accept any liability for damage resulting from the incorrect use of this accessory other than described in the present user manual.

These eye mask protective shells are worn through the operation of the device by the patient, not by the operator.

The eye mask must be correctly adjusted on the eyes of the patient.

The area covered by the eye mask protective shells must not be brought into contact with the hair, clothing or any other object, in order to avoid any risk of injury, obstruction or deterioration.

The product is designed in a way to optimize weight versus protection efficiency, taking into account that it is not known to cause adverse effects on the body by increasing muscle strain or energy consumption through increased or altered passive or dynamic loading. It is noted that patients, while wearing the product for the treatment, are not supposed to move during the treatment, except if it is required to do so, the practitioner must stop the treatment light source and patients must doff the eye mask before moving.

This product is not known to be used in compatibility of different types of PPE intended for simultaneous use as declared in this technical file and in the user instruction.

II. STORAGE, MAINTENANCE, CLEANING AND DISINFECTING

The cleaning, maintenance or disinfectant products shall be according to practitioner's instructions and requirements.

When not being used, the eye mask should be stored in its protective package and in a normal temperature condition.

III. ACCESSORIES AND MATERIAL DATA LIST

COMPONENT OR SUB-COMPONENT	MATERIAL
Shell (left)	Aluminium
Shell (right)	Aluminium
Shell Bridge	TPU
Shell fastener	TPU
Metal Clip	CRS
White cord	PP
Black snap joint	ABS

III. PRODUCT INFORMATION

1. Product ageing:

The product materials are selected for minimum ageing effects on performance. An ageing of the PET lens materials and frame materials over the time to be used at ambient conditions at workplaces is not reported. The assembled eye-protector shows no apparent deformation when heated up to about 55°C for 2 hours or when exposed to intense UV-radiation. Nonetheless, the eye mask may undergo a color change due to cleaning cycles that are not reported in the technical document. Therefore, it is advisable to stop using this product if any scratches on the eye contact part or any color change is noted, as described in the user manual.

In case of any incident: stop using if any deficiencies or damages to the product are noted - such as holes, breaks, scratches or if any part like the cord or the black snap joint are missing.

2. Product and Manufacturer:

Company name:	E-SWIN, Rue des Côtes d'Orval, ZA de la Prévôté, 78550 Houdan, France
Product:	EYE MASK
Type:	Eye Mask for medical laser applicaiton
Part number:	D000AZ006B00A
Marking:	315-1400DLB7+ILB8 ESWIN CE
Packaging:	Each eye mask is packaged in 1 polybag per 1 paper box with label.
Reference number of the certificate of notified body:	C1701.2ESWIN

3. Explanation of the symbols used in marking:

315-1400DLB7+ILB8	Wavelength range 315 – 1400 nm; LB- scale number to be tested conditions: D LB7 and I LB8.
E-SWIN	Name of the manufacturer.
CE	Conformity European marking.

4. Notified body of the conformity assessment of the product:

Notified Body 1883
ECS GmbH – European Certification Service
Huettfeldstraße 50
73430 AALEN, GERMANY

5. Levels and classes of protection:

This eye mask is used for protection against accidental exposure to laser radiation as defined and tested according to the requirements in the EN 207:2017 by ECS GmbH notified body at the spectral range of 315nm to 1400nm.

The classes of protection are defined by level performance which are tested under standards and specifications by ECS GmbH notified body.

6. Innocuousness:

Apart from the products specified in the technical documentation and in the user instructions, the products covered by the technical file are not known to contain materials or substances (including decomposition products) that may affect the health or hygiene of the user or any other person who may come into contact with the product.

Nevertheless, it may happen that very susceptible individuals show skin irritations or other allergic reactions after contact with the material used. No such case has been reported to the manufacturer.

7. Specific risks:

- It could not be used for any sport activities or sport safety.
- It could not be used for driving at all times.
- It could not be used in the conditions such as welding, electricity maintenance, steel grinding, cooking or some other heavy duty works.
- It could not be used to directly look at sunlight or laser light.
- It could not be used for any outdoor activities in any conditions.
- It could not be used for vision correction, ex. Myopia.
- It could not be used for protecting against natural UV-radiation.

EU DECLARATION OF CONFORMITY

The EU Declaration of Conformity (DoC) can be found on our website: www.e-swin.com/downloads or by scanning the QR-code below.

The QR code also provides access to the latest version of this user manual as well as user manuals in additional languages.



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