

User Information & User Manual

LOSKE Cura-T Face Shield

1. Introduction and intended use

The **LOSKE Cura-T – Face Shield** herein abbreviated **Cura-T** is a personal protective equipment (PPE) according to PPE Regulation (EU) 2016/425 protecting against droplets and splashes of liquids, if used properly. This reduces the risk of a droplet infection. Due to its design, full protection against viruses, bacteria or other biological agents is only given to a limited extent. **Cura-T** can be combined with breathing/respirator masks. **Cura-T** is to be used for applications in the medical field, nursing, rescue and other work areas affected by COVID-19 that require the same protective purpose.

Find the Declaration of Conformity (DoC) and the corresponding EU Type Examination Certificate of this product on our website <https://www.loske-muenchen.de/cura-t-download.php>.

2. Warnings

- **Cura-T** IS NOT INTENDED TO PROTECT AGAINST ANY KIND OF MECHANICAL IMPACT!
- use as a kit only,
- insufficient packing may decrease the level of protection; thus, follow the instructions as per Chapter 5.,
- material, which may come into contact with the wearer's skin, could cause allergic reactions to sensitive individuals.

Do not use the **Cura-T**, if:

- is torn, scratched, cracked or damaged in any way,
- is altered from its original form,
- has been exposed to chemicals, oils or lubes*,
- has been exposed to high heat or over exposed to sun light*.

* damages caused by the aforementioned incidents may not be visible to the end user.

3. Delivery contents

- Disposable high-transparent window *
- Reusable head band with clamping rail
- Bag (non sterile).

* Further replacement windows available.

4. Application and use

Cura-T is made of three components, the headband (light gray) with the clamping rail (dark gray) and the protective window. For assembling please perceive how the clamping rail is mounted to the headband and shove it downwards out of the headband slot. Insert the window in the now free groove of the headband so that the holes at the upper edge of the window are aligned with the small noses of the headband. Finally shove the clamping rail over the window in its initial position - that's it. Now adjust the clasp at the rear side of the headband to the circumference of your head so that the headband sits securely, but convenient at your head before entering the patient room or the nursing area. Take care that there is no hair, possibly contaminated clothing or other contaminated PPE underneath **Cura-T** in the facial area.

If you use **Cura-T** in combination with other PPE, carefully follow the instructions of the other PPE manufacturers. Carefully remove **Cura-T** before leaving the patient room or the care area. Avoid contact with contaminated surfaces. Dismantle **Cura-T**, dispose the contaminated window properly and disinfect the headband and the clamping rail separately with commercially available hand disinfectants

CAUTION: Some disinfectants are aggressive and may impair the headband and/or the clamping rail. Sometimes (but not for sure) impairments can be detected by changes of the component surface properties or color. Strictly follow the warnings and replacement criteria listed in Chapter 2.

5. Storage

For best results store **Cura-T** in the bag as used by **Loske**. (NOTE: Various other packing materials may contain softeners or solvents, which may affect **Cura-T**'s properties.) Store **Cura-T** out of sunlight or artificial UV light up to 3 years in a clean, dry environment between -5°C bis +40°C.

6. Standards and CE Marking

Cura-T is certified according to EN166:2001 - partly applied, according to the specific requirements to protect against the SARS-CoV-2 Virus, with the following Marking:

LOSKE 1 3 CE

i.e.

LOSKE	Manufacturer code (LOSKE GmbH)
1	optical class 1
3	Protection against splashes of liquids
CE	CE as per PPE Regulation (EU) 2016/425, Article 17 required for Cat. II products.

7. Important Addresses

<p>Manufacturer LOSKE GmbH Rappenweg 4, 81829 München Tel.: +49(0)89 - 430 40 61 Fax: +49(0)89 - 439 097 10 info@loske-muenchen.de www.loske-muenchen.de</p>	<p>Notified Body ECS GmbH Hüttfeldstr. 50 73430 Aalen Germany Phone +49 7361 9757396 Fax. +49 7361 5562434 info@ecs-eyesafe.de www.ecs-eyesafe.de</p>
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8. Hazards Assessment

In order to select appropriate eye and face protecting devices, a hazard and risk analysis shall be carried out by trained professionals and the eye, face and/or head protector never shall be used in environments with a higher risk rating than the protection rating indicated on the marking. According to this Hazard Risk Assessment, **Cura-T** shall be combined with further PPE such as protective overalls, breathing/respirator masks, gloves, etc.

9. REACH Declaration

The manufacturer ensures that the products described here and their packaging contain no substances to be included in accordance with Article 57 of the REACH Regulation (EC) 1907/2006 with a concentration of more than 0.1 mass percent (w/w), pursuant to Article 33 of this Regulation.

10. Disposal

After use discard **Cura-T** as "contaminated, mixed plastics".