1 Introduction

E-Guide Soft is a light-curing resin for the additive manufacturing of nasopharyngeal and oropharyngeal swabs. *E-Guide Soft* has been optimized for use with EnvisionTEC's *EnvisionOne cDLM and Perfactory® P4K series* 3D printers and may only be used together with these printers and the corresponding software systems. *E-Guide Soft* is a medical device classified as class 1 according to 21 CFR part 880. Swabs from *E-Guide Soft* may only be manufactured by qualified personnel and used on one person by authorized personnel.
The following Instructions for Use includes safety and environmental information, manufacturing instructions and post-processing procedures of the product, which must be strictly adhered to.

2 Indication

E-Guide Soft is intended for the additive manufacturing of nasopharyngeal and oropharyngeal swabs, which are used as medical devices for sampling nasal or pharyngeal secretions from the nasal or pharyngeal mucosa to detect a pathogen in suspected viral infections.
Swabs from *E-Guide Soft* are products for single use during the sampling of an allegedly sick person by authorized personnel at the doctor's, in hospital or at authorized contact points, taking into account of their application.
The minimum approved wall thickness is 0,5mm. After several printing processes the product may show slight color changes. However, this does not reduce the quality of the application.

3 Contraindication

E-Guide Soft may only be used for the production of nasopharyngeal and oropharyngeal swabs in medical industries. Any deviation from the Instructions for Use can negatively affect the chemical and physical properties. Consequently, the biocompatibility of the nasopharyngeal and oropharyngeal swabs cannot be guaranteed.
E-Guide Soft may not be used for the manufacturing of further products.

For patient and users:
Patients, users or third parties who come in contact with products from *E-Guide Soft* must be informed about any side effects before use. *E-Guide Soft* products may not be used if there are known allergies to any of the ingredients, otherwise possible side effects such as shortness of breath, gastrointestinal complaints, dizziness, anaphylactic reactions or shocks, itching and tearing (watery) eyes, headaches or reactions of the skin or mucous membrane such as irritation, rash, swelling, inflammation, redness, wheals or blisters or other allergic reactions may occur.

4 Composition

Acrylate/Methylacrylates, methacrylated Oligomers and Monomers, photo initiators, colorants/dyes and absorbers.

5 Hazard and Precaution statements

Danger:

Causes skin irritation.
May cause an allergic skin reaction.
Causes serious eye damage.
May cause respiratory irritation.
Suspected of damaging fertility.
Suspected of damaging the unborn child.

Precaution:

Wear protective gloves, protective clothing, eyes protection, face protection.

First Aid:

If on skin wash with plenty of water.
If in eyes rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If swallowed, immediately call poison center.

6 Storage Conditions and Expiry Date

The resin needs to be stored in the original bottle between 41 – 86 °F. While removing the resin it must be protected from exposure to light, as spontaneous self-polymerization is possible. The bottle must be tightly closed after every usage and material removal. Resin inside the machine basement can be re-used for several build jobs. If the level in the basement is too low for subsequent jobs, resin from the bottle can be added as necessary. If the material is not in use, it must be poured back into the bottle. For further information on re-using and mixing material, please check the machine manual. The use of expired material is not permitted. The nasopharyngeal and oropharyngeal swabs need to be protected from exposure to light before the final use.

7 Notes on Disposal

Dispose of contents and container in accordance with local regulation.
The manufactured nasopharyngeal and oropharyngeal swabs, which are used on patients must be disposed properly due to the risk of infection (contaminated by substances of human origin).

8 Sterilization Instructions

The swabs made of *E-Guide Soft* must be sterilized before being used as intended. The autoclave must be used in accordance with the manufacturer`s instructions (e.g. 250 °F / 15 min.).

9 Use of Software Systems and Products from Other Manufacturers

The use of certified software systems for generating the STL-data and the use of additional products depends on user's assessments.

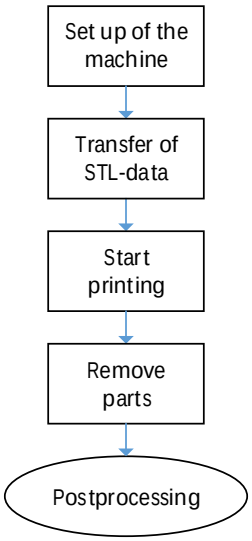
10 Delivery Unit, Symbol Explanation and Manufacturer Information

Delivery unit: *E-Guide Soft* is available in containers of 1 kg

Symbol explanation:

LOT	Batch number		Protect from sunlight
	Expiration date		Follow Instructions for Use
	Manufacturer		Temperature limit
REF	Purchase order number		Production date
Rx Only	Prescription device labeling statement	UDI	Unique device identification

11 Manufacturing Process



Setup machine for the resin (see machine manual) and fill the polymer tray/basement. To avoid impurities, resin mixes and contamination a separate polymer tray/basement must be used.

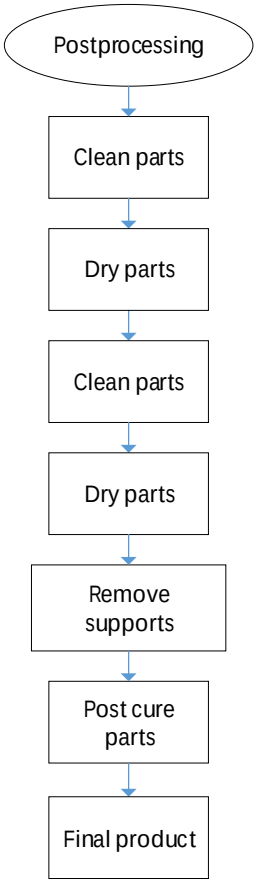
Transfer constructed STL-files for the nasopharyngeal and oropharyngeal swabs to the machine (see machine/software manual) *.

Start the printing process as described in the machine manual.

When the printing is done, remove the parts carefully from the platform.

* The scanning and construction of STL data is the responsibility of the customer. We recommend that only trained personnel perform the scanning and design. Further, a certified software is recommended. To generate the support structures if necessary, we recommend the EnvisionOne RP (version 1.0.1165 or later).

12 Postprocessing



Cleaning in 2-propanol (min. >96 %) (max. 5 minutes); Cleaning in ultrasonic bath); Recommendation: Pour 2-propanol into a beaker and place in an ultrasonic bath. Clean and rinse gaps separately.

Dry with compressed air.

Cleaning in 2-propanol (min. >96 %) (max. 5 minutes); Cleaning in ultrasonic bath); Recommendation: Pour 2-propanol into a beaker and place in an ultrasonic bath. Clean and rinse gaps separately.

Dry with compressed air. Place the dried part in an incubator/oven at 98 °F for 30 minutes.

Remove the supports with a scalpel or similar tool.

Light curing unit: PCA 2000 or PCA 4000; Parameters: 15 min. at 140 °F;

The component is now ready for the final assembly and can be finished together with the associated parts, components and accessories.

Finally, the swabs can be used on one person, taking into account of their preparatory measures.

The used equipment, machines, utensils and materials must be maintained, calibrated, serviced and checked for expiration date before use according to the manufacturer's or standard specifications. The use of alternative exposure devices can lead to changes in the properties of the final product. Manual corrections by material removal are not permitted.

13 Reporting Undesirable Effects

In the event of adverse effects, reactions or similar occurrences arising from the use of this products, including those not listed in this Instructions for Use must be reported immediately by opening a support ticket via out website https://envisiontec.com/ or by contacting your local distributor.

14 Manufacturer

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