

NANOLITE

Product/Type: Composites

Rev.19.06.2025

Description: 3D printing composite

Intended use: Substance for the preparation of customized dental devices - others

Medical Device: Class IIA Medical Device - Long-term implantable.

1. General Informations

The package contains Nanolite, a material for the creation of customized dental devices. Its use in the dental field is widely described in the literature, and there are no indications or residual risks reported.

The use of these materials is reserved for qualified personnel who:

- Is responsible for determining the suitability of the product for the required application.
- Before using any product, you must equip yourself with the appropriate Personal Protective Equipment (overall, plastic gloves and masks to protect the respiratory tract from dust)
- It must be used as indicated in paragraph 2. Operational protocol, where the other necessary elements are also mentioned

The products must be stored in the original packaging, in a temperature range from +5°C to +25°C, protected from heat and light sources.

The user must report any serious incident occurring in relation to the device to the manufacturer and to the competent authority of the Member State where the user is established. The product was created for use in the dental field and must be used according to the instructions for use. The manufacturer assumes no responsibility for damage resulting from use not in accordance with these instructions. The user is required to personally check the suitability of the product for the uses intended by him, if these uses are not reported in the instructions for use.

2. Operating Protocol

Before starting 3D printing, make sure to mix nanolite: Mixing can be done directly in the print tank using a spatula or by gently shaking the package containing nanolite. For best results, we recommend keeping the nanolite temperature at 25°C or higher.

After the printing process, carefully take the printed piece and clean it with isopropilic alcohol or alcohol 96%.

Final Cure step: 10 minutes (wavelength 350/500nm, power 4000/16000nWs/cm2, always check the efficiency of the lamps), 100% intensity, 60° C.

Remove the print supports with a diamond disc and suitable cutters and finish the denture with diamond or tungsten carbide burs.

To add composite or stains to the printed denture, proceed as follows: sandblast the denture with 150 micron aluminum oxide, use 96° ethyl alcohol to thoroughly degrease and clean the surface (dry thoroughly), apply a small amount of UNIBOND adhesive (dry thoroughly), apply the composite or stains (follow the manufacturer's instructions), and, once finished, polish the surface with soft cotton brushes and a polishing paste such as Micro Bright by Micro.Medica.

3. Warnings

Caution: Do not use different resins to change the viscosity of the composite.

For the Summary of Safety and Clinical Performance please consult the EUDAMED database.

Storage Notes: Do not use after expiration. **Expiration:** see date shown on the packaging.

Temperature and storage: from +5°C to +25°C, protected from heat and light sources. **Protect from direct sunlight. Close immediately after use, exposure to light causes premature curing.**

4. Disposal

The device must be disposed according to local regulations, in Europe in the framework of Directive 2008/98/EC.

5. Symbols and warnings



Safety advices: Always use suitable clothing and protective devices, protect your eyes with appropriate glasses, do not inhale dust, use a specific vacuum cleaner for finishing, wear a mask and protect your hands with gloves. Avoid contact of the uncured composite with the skin/mucous membranes and eyes. In its uncured state, the composite may have a slight irritant effect and lead to sensitization to methacrylates. May cause reactions in patients sensitive to the product.

Warranty: Micro.Medica S.r.l. guarantees that this product is free from manufacturing defects.

Micro.Medica S.r.l. makes no other warranties including any warranties of merchantability or fitness for a particular purpose. The user is responsible for determining the suitability of the product for the required application. If the product is defective, within the warranty period, Micro Medica S.r.l. will replace it. Micro Medica will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory alleged, including warranties, contracts, negligence or strict liability.

Keep out of reach of children. - Product for professional use.

This instruction is valid for the following codes:

MGCX61A1, MGCX61A2, MGCX61A3, MGCX61B1, MGCX62A1, MGCX62A2, MGCX62A3, MGCX62B1, MGCX63A1, MGCX63A2, MGCX63A3, MGCX63B1, MGCX61PL, MGCX61PM, MGCX61PD, MGCX62PL, MGCX62PM, MGCX62PD, MGCX63PL, MGCX63PM, MGCX63PD.

(The code is found on the label next to the **REF**)