Desktop Health™

Instructions for Use – Flexcera® Smile Ultra+
Light Curable Resin

1. – Introduction

Flexcera® *Smile Ultra+* is a light-curing resin for the additive manufacturing of:

- artificial teeth for dental prostheses, which are one of the main components in the fabrication of removable permanent full dentures.
- individual permanent full single crowns and permanent partial crowns in anterior and posterior region, including inlays and onlays.
- temporary bridges including implant supported bridges.
- individual permanent veneers.
- individual and removable monolithic full and partial dentures for later individualization by light curing color composite pastes or liquids.

It has been optimized for use with released 3D Printers (see section 11-A-1) and may only be used together with these printers and the corresponding software systems. **Flexcera® Smile Ultra+ is a medical device classified as class IIa according to Regulation (EU) 2017/745**. Dental applications from **Flexcera®** *Smile Ultra+* may only be manufactured by dental technicians and dentists, and must be inspected by authorized practitioners, such as dentists, before they are released to the patients.

Temporary applications from **Flexcera®** *Smile Ultra+* are custom-made products that may be used up to one year, under consideration of their application and intended exclusively for one patient. Dental applications from **Flexcera®** *Smile Ultra+* are custom-made products for long-term use, under consideration of their application and intended exclusively for one patient. The target group is patients which need restorations or optimization of the teeth, whereby high-risk patients are excluded (see Section 3). The use of the medical device is independent of the age and sex of the patient. The decision related to the patient application is at the discretion of the respective medical specialist.
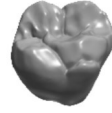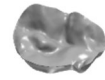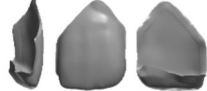
The following Instruction for Use includes safety and environmental information, manufacturing instructions, and post-processing procedures of the product, which must be strictly adhered to.
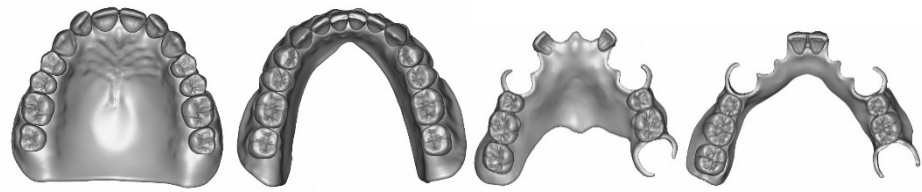
2. – Indication

Flexcera® *Smile Ultra+* is an alternative to traditional heat-curable and auto polymerizing resins. The resin is intended exclusively for professional dental work. Fabrication of dental applications with *Flexcera*® *Smile Ultra+* requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital dental files based on a digital impression or, in case of artificial teeth for dental protheses, digital dental files based on manufacturer's data, a digital light processing (DLP) printer, and curing light equipment.

Authorized applications:

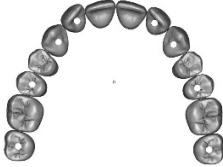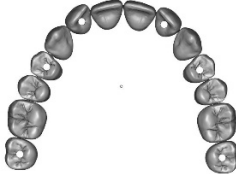Crowns, Veneers:

Full anatomical single crown in anterior region	Full anatomical single crown in posterior region	Partial crown (Inlay/ onlay /overlay)	Veneer

Artificial teeth, monolithic full and partial dentures:

Artificial teeth for dental protheses	Monolithic full and partial dentures* * monolithic full dentures even implant supported

Bridges:

Full anatomical monolithic bridge for anterior and/or posterior region <u>with no pontic</u> (e.g. 6-unit bridge)	Full anatomical monolithic bridge for anterior and/or posterior region with pontics and/or implant supported (e. g. implant supported full arch bridges or other implant supported bridges)

Flexcera® *Smile Ultra+* is available in the following colors:

Bleach		
A1		**Flexcera®** *Smile Ultra+ A1* is comparable to VITA® classical, colors A1, C1, D2 Dentin
A2		**Flexcera®** *Smile Ultra+ A2* is comparable to VITA® classical colors A2, D4 Dentin
A3		**Flexcera®** *Smile Ultra+ A3* is comparable to VITA® classical colors A3, B3 Dentin
A3.5		**Flexcera®** *Smile Ultra+ A3.5* is comparable to VITA® classical colors A3.5, B4 Dentin
B1		**Flexcera®** *Smile Ultra+ B1* is comparable to VITA® classical color B1 Dentin

3. – Contraindications

Flexcera® Smile Ultra+ should not be used for purposes other than those identified herein. Any deviation from these instructions for use may have negative effects on the physical and/or chemical qualities of the resin and the biocompatibility of the end product. Dental applications from *Flexcera® Smile Ultra+* should not be used in patients if there are known allergies to any of the ingredients (see Section 4). Possible side effects may include shortness of breath, gastrointestinal complaints, dizziness, anaphylactic reactions, or shocks, itching and tearing (watery) eyes, headaches, or reactions of the skin or mucous membranes such as irritation, rash, swelling, inflammation, redness, wheals or blisters or other allergic reactions.

4. – Composition

Acrylates, methylacrylates, methacrylated oligomers and monomers, photo initiators, colorants/dyes, fillers and absorbers.

5. – Warnings

- Review the SDS prior to use.
- *Flexcera® Smile Ultra+* may only be used for the production of:
    - artificial teeth for dental protheses, which are one of the main components in the fabrication of removable permanent full dentures.
    - individual and fixed temporary or permanent full single crowns and temporary or permanent partial crowns in front and posterior area.
    - temporary bridges including implant supported bridges.
    - individual and fixed single veneers.
    - individual and removable monolithic full and partial dentures for later individualization by light curing color composite pastes or liquids.
- Any deviation from the Instruction for Use can negatively affect the chemical and physical properties and biocompatibility of the finished product.
- Do not substitute any of the components of the device system, i.e., device photopolymer materials, scanners, 3D printers, post-curing units, CAD/CAM software, templates, and tools. Use only those specifically identified in this labeling. Unauthorized changes may result in a device that is outside of specification. Contact the manufacturer for compatible components.
- Maintain and calibrate equipment according to manufacturer instructions.
- Products from *Flexcera® Smile Ultra+ light curable resin* cannot be sterilized. See section 12 for disinfection procedure.
- Wear protective gloves, protective clothing, eye protection, face protection while handling *Flexcera® Smile Ultra+ light curable resin*.
- In case of skin contact with the resin, wash with plenty of water.
- In case of eye contact, rinse cautiously with water for several minutes. Remove contact lenses, if necessary and easy to do. Continue rinsing. Consult a physician.
- If swallowed, immediately call the poison center.
- Any patients who come in contact with products from *Flexcera® Smile Ultra+ light curable resin* must be informed of potential side effects before use (see Section 3).

6. – Precautions

- Wear protective gloves, protective clothing, eye protection, face protection.

- Use in appropriately ventilated area. Avoid breathing dust/fume/gas/mist/vapors/spray.

- *Flexcera® Smile Ultra+ light curable resin* must be stored in the original material bottle between 41°F (5°C) and 86°F (30°C).

- *Flexcera® Smile Ultra+ light curable resin* must be protected from exposure to light, as spontaneous polymerization is possible. The bottle must be tightly closed after every usage and material removal. The resin must be used prior to the expiration date printed on the label.

- As described in chapter 7, when using an *Einstein*™ 3D printer, mix the remaining material in the material tray thoroughly after no more than 4 builds and return it to the bottle. Shake the bottle vigorously.

- Dental applications from *Flexcera® Smile Ultra+* must be protected from exposure to light while not in use.

7. – Storage Conditions, Expiry Date and Re-use of Material

- *Flexcera® Smile Ultra+ light curable resin* must be stored in the original material bottle between 41°F (5°C) and 86°F (30°C).

- While removing the resin it must be protected from exposure to light, as spontaneous polymerization is possible. The bottle must be tightly closed after every usage and material removal.

- An expiration date is displayed on the label of every material bottle. The use of expired material is not permitted.

- The resin inside the material tray or resin tank can be re-used for several build jobs. If the level in these 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 filled back into the bottle. For further information on re-using and mixing material, please check the printer's *User Manual*.

- When using an *Einstein*™ 3D printer, mix the remaining material in the material tray thoroughly after no more than 4 builds and return it to the bottle. Shake the bottle vigorously.

- Dental applications from *Flexcera® Smile Ultra+* need to be protected from exposure to light before the final use, while not in use and during storage.

8. – Notes on Disposal

Dispose of *Flexcera® Smile Ultra+ light curable resin* and material bottle in accordance with local regulation. Manufactured dentures which are used on patients must be disposed of in accordance with local regulation due to the risk of contaminated by substances of human origin.

9. – Use of Software Systems and Products from Other Manufacturers

The use of certified software systems for generating the STL data, as well as the use of any other additional medical products or auxiliary products to manufacture crowns, veneers, artificial teeth for dental protheses and monolithic full and partial dentures, such as e.g. light-curing stains and composites for individualization, bonding agents for fixing artificial teeth with denture base, luting composite for bridge, crown or veneer fixing, material for full denture bases or implants and abutments as retaining element inside patients mouth etc. depends on the user's assessments.

10. – Delivery Unit, Symbol Explanation

Delivery unit: **Flexcera**® *Smile Ultra+* is available in containers of 0.5 kg and 1 kg.

Symbol explanation:

LOT	Batch number	☀	Protect from sunlight
⧗	Expiration date (YYYY-MM-DD)	📖i	Follow Instruction for Use
🏭	Manufacturer	🌡	Temperature limit
REF	Catalogue number	∿	Manufacturing date (YYYY-MM-DD)
CE	CE-Mark	UDI	Unique device identification
MD	Medical Device		

11. – Manufacturing Instructions

A. SUPPLIES NEEDED

1. Released 3d Printer:
   1. Desktop Health 3D printer
   2. EnvisionTEC 3D printer
   3. Asiga® Max-series, Ultra-series, and Pro 4K-series
   4. LuxCreo iLux Pro Dental and LuxCreo fastprint.io printer
   5. DentaFab Sega Pro

2. Material tray or resin tank (LuxCreo and DentaFab) for use with *Flexcera® Smile Ultra+ light curable resin* only.

3. *Flexcera® Smile Ultra+ light curable resin*.

4. *Flexcera® Base* or *Base Ultra+ light curable resin*, or conventional denture base materials, if fabricating artificial teeth for dentures.

5. *Flexcera® Smile Ultra+* material tag/RFID card (shipped with the material bottle and only for usage on Desktop Health™ or EnvisionTEC 3D Printer)

6. Released Software:
   1. Perfactory® RP Software (version 3.1540.1602 or later)
   2. Envision One RP (version 1.0.1165 or later)
   3. Live Build DLP (version 2.0.102 or later)
   4. Cambridge Software from 3Shape A/S (version 2015 2650 or later)
   5. Asiga® Composer
   6. LuxFlow Software
   7. Chitubox Basic Software (2.3 or later) & Megaplatform remote controller (v.1.0.21)

7. Buildstyle (EnvisionTEC or Desktop Health™), .ini file (Asiga®), Print Parameter (LuxCreo) or Profile (DentaFab) for *Flexcera® Smile Ultra+.* Contact EnvisionTEC Technical Support if buildstyle is not supplied with the machine or download the .ini file the user section of the Asiga® website (www.asiga.com) or add the profile to your machine via NovaHub for your DentaFab Sega Pro Printer.

8. File in .stl format or in slc format for DentaFab Sega Pro Printer.

9. Starter Kit (included with the purchase of the 3D printer).

10. Paper towels.

11. Cone-shaped funnel.

12. Personal protective equipment, as per SDS.

13. Magnetic stirrer with bar, or lab shaker.

14. Isopropyl Alcohol min. >96%.

15. Post curing unit:
    1. Otoflash G171
    2. Wicked Engineering CUREbox Plus
    3. Dreve PCU LED N2 curing unit
    4. iLuxCure Pro or iLuxCure Dental

16. Pipette.
17. Standard dental polishing equipment.

B. DESIGN INFORMATION

The scanning and construction of patient STL data is the responsibility of the customer. Only trained dental personnel must perform the scanning and design. Further, certified software must be used, such as from e.g., 3Shape A/S.

Construction rules

Crowns and veneers:

Crowns made of **Flexcera**® *Smile Ultra+* must be adhesively fixed to a prepared natural tooth stump or an artificial tooth stump such as an implant abutment or post and core.
Veneers made of **Flexcera**® *Smile Ultra+* must be adhesively fixed to a prepared natural tooth stump.

Minimum wall thickness
Occlusal: 1.5 mm in central fissure
Circular: 1 mm

Parts must be built horizontally orientated to the platform, with supports connecting only to the occlusal or incisal surface e.g., to avoid manual post processing of the sides in direct contact with the mating surface.

Monolithic full dentures:

Monolithic full dentures made of **Flexcera**® *Smile Ultra+* must be designed without any additional fixtures to increase holding force. Design the denture base using the certified software based on the digitalized data obtained from the bite registration process. **The minimum approved wall thickness is 2.5mm**.

Parts must be built vertically orientated to the platform, with supports connecting only to the labial border, to avoid manual post processing of the sides in direct contact with oral mucosa.
A connector must be added to the design of the lower denture base to ensure the stability of the part during fabrication and accuracy of the part's dimensions/fit once finished. The connector designs in *Fig. 1* are permitted (Figure 1A is recommended, as it will require the least amount of material while ensuring high accuracy).

FIG. 1 VALIDATED CONNECTOR DESIGNS FOR LOWER DENTURE BASE

FIG. 1 VALIDATED CONNECTOR DESIGNS FOR LOWER DENTURE BASE

Monolithic partial dentures:

Monolithic partial dentures made of *Flexcera® Smile Ultra+* must be designed without any additional fixtures to increase holding force, except for the clasps. **The minimum approved wall thickness of the denture as well as for the clasps is 2.5mm**.

Bridges:

The temporary bridges made of *Flexcera® Smile Ultra+* must continuously consist of full anatomical crowns, need to be end pillar bridges and need to be adhesively fixed to the bridge pillars (prepared natural tooth stump and/or an artificial tooth stump) e.g. "Toronto bridge or other implant supported bridges."

Minimum connector cross-section
Anterior region: 12 mm²
Posterior region: 14 mm²

Minimum wall thickness
Occlusal: 1.5 mm in central fissure
Circular: 1 mm

Parts must be built horizontally orientated to the platform, with supports connecting only to the occlusal or incisal surface e.g., to avoid manual post processing of the sides in direct contact with the mating surface.
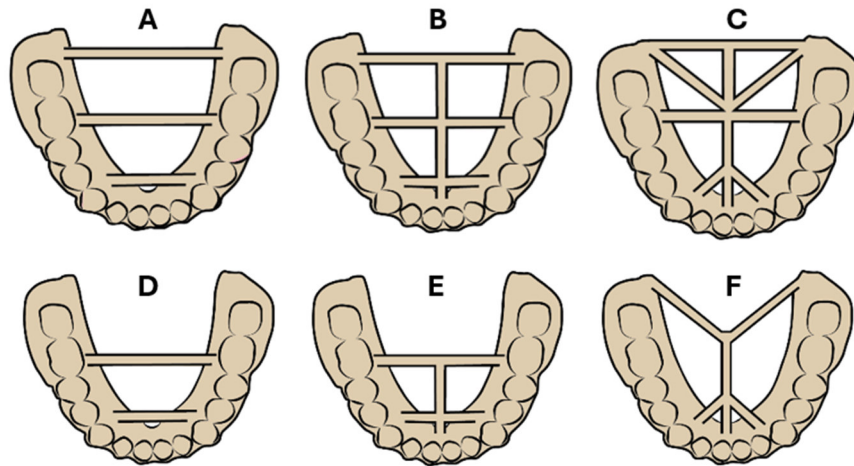
C.   PREPARING TO PRINT

Preparing the Material:

Flexcera® Smile Ultra+ light curable resin must be properly mixed before use.

Prepare the material: Before using this material for the first time or after prolonged storage, it must be homogenized. Shake the material bottle vigorously for approximately 5 minutes. Be aware that vigorous shaking may cause air bubbles to form. Allow the material to rest in the bottle for an additional 5 minutes to allow any air bubbles to rise and dissipate before use.

Preparing the 3D Printer:

Setup the 3D printer for **Flexcera**® *Smile Ultra+ light curable resin* (s*ee the User Manual for the specific 3D printer used*). Fill the material tray or resin tank. Use the spatula from the Starter Kit or a material mixing card if available to carefully mix the resin in the material tray or resin tank. Mix until there is a uniform color. Take care not to damage the surface of the material tray or resin tank.

To avoid contamination, a separate material tray or resin tank dedicated to **Flexcera**® *Smile Ultra+* material must be used.

A material tag (RFID card) is shipped with the **Flexcera**® *Smile Ultra+* resin bottle. Place the material tag on the RFID tag reader on the 3D printer if it is required. The card must remain on the reader for the duration of the print.

Preparing the STL for 3D printing, Software Considerations:

To prepare the .stl file for 3D printing and generate the support structures, use a released software (see section 11-A-6).

Connect the **Flexcera**® *Smile Ultra+* buildstyle (EnvisionTEC or Desktop Health™), .ini file (Asiga®) or Print Parameter (Luxcreo) to the corresponding Software. Contact EnvisionTEC Technical Support to receive a buildstyle for **Flexcera**® *Smile Ultra+* or download the .ini file in the user section of the Asiga® website. For DentaFab Sega Pro Printer please follow the printer instruction.

Transfer constructed STL files of planned applications to the printer. *See the printer s User Manual / Software User Manual.*

D.   STARTING THE PRINT

Start the printing process as described in the *printer s User Manual*.

E.   REMOVE PARTS FROM PRINTER

When the printing process is complete, carefully remove the parts from the build platform.

NOTE: Always wear personal protective equipment when interacting with uncured material.

1. Open the printer's hood.
2. Remove the build platform from the printer.

Place the build platform on a sturdy surface. Use the provided scraper from the Starter Kit to carefully remove all parts from the build platform. Place parts on a clean paper towel and protect from ambient light.

F.   CLEANING THE PARTS

Set up the magnetic stirrer with a bar or lab shaker in the Post Processing area and add Isopropyl Alcohol (min. >96 %) into an appropriately sized container. *See the stirrer / shaker manual for setup instructions.*

Clean the parts using the following procedure:

1. Clean in Isopropyl Alcohol (min. >96 %) for a maximum of 5 minutes in the stirrer or lab shaker (no ultrasonic bath). Clean and rinse gaps separately under pouring conditions.

2. Dry with compressed air.

3. Clean in Isopropyl Alcohol (min. >96 %) for a maximum of 2 minutes in the stirrer or lab shaker (no ultrasonic). Clean and rinse gaps separately under pouring conditions.

4. Dry with compressed air.

5. Parts must be completely dry before post-curing, e.g. airdry @15min.

6. Remove the supports with a scalpel or similar tool.

G. WHEN PRINTING ARTIFICIAL TEETH FOR DENTURES

ASSEMBLING THE DENTURES:

Artificial teeth printed with **Flexcera**® *Smile Ultra+* may be bonded to denture bases printed with **Flexcera**® *Base light curable resin* or conventional denture base materials.

If using Flexcera® Base (*see* **Flexcera**® *Base IFU for manufacturing instructions***)**:

1. The 3D printed dentures and the printed artificial teeth must be uncured and unpolished prior to adding bonding agent (optional) and attaching to the denture.

2. Use the pipette to place drops of uncured **Flexcera**® *Base* in the alveoli.

3. Immediately after place the teeth over the liquid photopolymer.

4. Follow with the step "Post-cure options"

If using Flexcera® Base Ultra+ (*see* **Flexcera**® *Base Ultra+ IFU for manufacturing instructions***)**:

1. The 3D printed dentures and the printed artificial teeth must be uncured and unpolished prior attaching to the denture.

2. Use the pipette to place drops of uncured **Flexcera**® *Base Ultra+* in the alveoli.

3. Immediately after place the teeth over the liquid photopolymer.

4. Follow with the step "Post-cure options"

If using conventional denture base materials:

1. The artificial teeth need to be post cured with the listed units, (see section 11-A-15).

2. The tooth neck may be sandblasted or ground with a dental milling machine prior to adding a bonding agent.

3. A bonding agent must be used to coat the tooth neck.

4. The Instuction for Use of the conventional denture base material has to be followed (Recommendation: Cold polymerization process).

Post-cure options:

When bonding to *Flexcera Base* Post-cure the part using the light curing units:

    a) Otoflash G171; Parameters: 2x3000 flashes (i.e., 3000 flashes per side); Recommendation: under inert gas (e.g., nitrogen)

       OR

    b) Wicked Engineering CUREbox Plus: Parameters: 2x 25minutes with 50°C (25minutes per side)

       OR

    c) Dreve PCU LED N2, Parameters: 90% Power for 18 minutes under vacuum.

When bonding to *Flexcera Base Ultra+* Post-cure the part using the light curing units:

    a) Otoflash G171; Parameters: 2x4000 flashes (i.e., 4000 flashes per side); Recommendation: under inert gas (e.g., nitrogen)

       OR

    b) Wicked Engineering CUREbox Plus: Parameters: 2x 20minutes with 45°C (20minutes per side)

       OR

    c) Dreve PCU LED N2, Parameters: 90% Power for 18 minutes under vacuum.

       OR

    d) iLuxCure Pro for 10 min with 100%

       OR

    e) iLuxCure Dental Program Setting P08 (12min with 35% power)

H. Finishing the dentures:

1. Use a commercial dental handpiece to clean the remaining support structures and remove excess resin around the teeth.

2. Optional: Individualize with light-curing coloring materials for a better cosmetic effect, according to the Instruction for Use of the color material manufacturer.

3. High gloss polish the surface with a commercially dental hand piece or dental polishing machine.

4. Post-cure the product in the Otoflash G171 with 1000 flashes, with the Wicked Engineering CUREbox Plus for 5 minutes without temperature, in the Dreve PCU LED N2 with 90% power for 3 minutes under vacuum, with the iLuxCure Pro or iLuxCure Dental for 1min with 50% power.

5. The product can now be used on the patient.

   The post-curing process may cause minor temporary color deviation of artificial teeth built using ***Flexcera*® *Smile Ultra+***. The color will stabilize within 6 days.

I. WHEN PRINTING ARTIFICIAL TEETH, CROWNS, VENEERS, BRIDGES AND MONOLITHIC DENTURES

1. Post-cure the part using the light curing unit:

2. Otoflash G171; Parameters: 2x3000 flashes (i.e., 3000 flashes per side); Recommendation: under inert gas (e.g., nitrogen), Wicked Engineering CUREbox Plus: Parameters: 2x 25minutes with 50°C, Dreve PCU LED N2 Parameters: 90% Power for 18 minutes under vacuum, with the iLuxCure Pro for 10 min with 100% power or iLuxCure Dental Program Setting P08 (12min with 35% power).

3. For lower full dentures only: Remove the connector with a scalpel or similar tool.

4. Optional: Individualize with light-curing coloring materials for a better cosmetic effect, according to the Instruction for Use of the color material manufacturer.

5. High gloss polish the surface with a commercially dental hand piece or dental polishing machine.

6. Post-cure the product in the Otoflash G171 with 1000 flashes, with the Wicked Engineering CUREbox Plus for 5 minutes without temperature, in the Dreve PCU LED N2 with 90% power for 3 minutes under vacuum, with the iLuxCure Pro or iLuxCure Dental for 1min with 50% power.

7. The product can now be used on the patient.

The post-curing process may cause minor temporary color deviation of printed dental parts built using **Flexcera**® *Smile Ultra+*. The color will stabilize within 6 days.

12. – Disinfection and Sterilization

Printed dental parts made of **Flexcera**® *Smile Ultra+ light curable resin* can be disinfected with any of the following disinfectants:

*   70 % Ethanol solution in water

*   Green&Clean AD

*   MD 520

*   PrintoSept-ID

*   Dentavon

The disinfecting solutions must be used according to the manufacturer's instructions.

Products from **Flexcera**® *Smile Ultra+ light curable resin* cannot be sterilized.

13. – Cleaning Instructions for Dentures

The denture can be cleaned by the patient with clear water, a toothbrush, and toothpaste. Avoid abrasive or whitening agents in some kinds of toothpaste which can damage the surface of the denture. After cleaning with clear water, the denture should be dried and not soaked in liquid.

Note: Care should be taken to ensure that the dentures are not shipped or stored soaking in water as this can adversely affect the mechanical properties.

14. – Reporting undesirable effects

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

15. – Manufacturer

EnvisionTEC GmbH

Brüsseler Str. 51	Telephone:	+49-(0)2043-98750
45968 Gladbeck	E-Mail:	info@envisiontec.de
Germany	Website:	www.envisiontec.com

16. – Legal Disclaimer

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