

<b>Graphy</b>	IFU(Instructions For Use)	Sta No.	GRPIFU-002
		Rev Date	2022-06-30
	Tera Harz Clear TC-85 Resin for orthodontic devices	Rev No.	3
		Page	1/6

R e v i s i o n H i s t o r y	Rev #	Approved Date	Reasons for revision	Description	Remarks
	0	2019-10-08	First inacted	Established to accommodate medical device manufacturing and quality management system in our management system	
	1	2020-03-09	Revision	Amendment according to supplementary application of CE audit	
	2	2020-09-14	Revision	Change label design	
	3	2022-06-30	Revision	Change (Extended shelf life)	

	Name	Department	Date	Signature
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Approved by	Sim, Un seob	CEO	2022-06-30	

※ This document is effective from the date of approval.

<b>Graphy</b>	IFU(Instructions For Use)	Sta No.	GRPIFU-002
		Rev Date	2022-06-30
	Tera Harz Clear TC-85 Resin for orthodontic devices	Rev No.	3
		Page	2/6

## 1. Preface

The manual of Tera Harz TC-85 for a dental calibration device such as clear aligner and it is for Dental experts such as a Dentist and an Orthodontist. This manual also contains a guideline of material safety and material environment. For the safety data sheet, please check [www.itgraphy.com](http://www.itgraphy.com) or find it at local distributors.

## 2. Introduction

Tera Harz TC-85 is a high molecular material based on urethane acrylate oligomers and the resin is suitable to produce a dental calibration device such as clear aligner with 3d printer. The material is CE classIIa certified.

## 3. Identification of device(s)

Product name : Orthodontic preformed Direct Aligner

Proprietary name : TERA HARZ CLEAR

Model(s) : TC-85DAC (Available in color Clear)  
TC-85DAW (Available in color White)

## 4. Intended use/ Instruction for Use

TERA HARZ CLEAR is intended for the correction of dental malocclusion in patients with permanent dentition. The TERA HARZ CLEAR is intended for teeth movement by way of continuous gentle force. TERA HARZ CLEAR is a monomer as a biocompatible material based on Acrylic esters indicated for manufacturing of all types of orthodontic aligner and positioners bases in dental laboratories. Fabrication of these prostheses require a manufacturing of all laser and DLP based 3D printers.

## 5. Description and effect

Tera Harz TC-85 Graphy material is suitable for all type of 3d printers such as LCD, DLP and SLA.

<b>Graphy</b>	IFU(Instructions For Use)	Sta No.	GRPIFU-002
		Rev Date	2022-06-30
	Tera Harz Clear TC-85 Resin for orthodontic devices	Rev No.	3
		Page	3/6

## 6. Contraindication

TERA HARZ CLEAR should not be used for any other purpose than temporary dental appliances only. Any deviation from this instruction for use may have negative effect on the chemical and physical quality of TERA HARZ CLEAR. In case of an allergic reaction, please contact a medical physician.

## 7. Adverse effects

Product may cause allergic reactions.

## 8. Precautions required by the manufacturer

Inhalation : Irritating to respiratory system. High atmospheric concentrations can cause to irritation of the respiratory, dizziness, headaches and anesthetic effects.

Skin contact : May cause sensitization by skin contact. Irritation to skin, repeated or prolonged contact may cause dermatitis.

Eye contact : High vapor concentration may cause irritation.

Ingestion : Low oral toxicity, but ingestion may cause irritation of the gastrointestinal tract.

Protection : Wear protection when handling TERA HARZ. Protective glasses and nitrile gloves are advised.

## 9. Hazard Phrases

H317 May cause an allergic skin reaction

H413 May cause long lasting harmful effect to aquatic life

## 10. Storage conditions, expiry date and transport.

Store the product in the original packaging at room temperature in a dry and dark area, preferably in 15-25°C. Close the packaging after each use. The expiry date of the product is mentioned on the product label. In case of exceeding the expiry date, the product is no longer guaranteed in terms of treatment.

<b>Graphy</b>	IFU(Instructions For Use)	Sta No.	GRPIFU-002
		Rev Date	2022-06-30
	Tera Harz Clear TC-85 Resin for orthodontic devices	Rev No.	3
		Page	4/6

## 11. How the device achieves its intended purpose

- 1) Fill appropriate amount of the resin into the material-VAT in the chamber of a 3D printer.
- 2) Operate the 3D printer machine.
- 3) After 3D printing, remove the build-plate from the equipment.
- 4) Use the removal tool for separating the output from the build-plate.
- 5) Remove the support from the output.
- 6) Wipe the output with a fine brush.
- 7) If it is necessary to increase density of the surface output, please do nitrogen-curing upper and lower parts within 2 min each.
- 8) According to the size and shape of the output, please do UV curing within 60 min to upper and lower parts of the output in the UV curing machine.

After this step, you can get the fully completed output with high mechanical properties.

### Tera Harz Clear – Condition of UV curing time

Tera Harz	Time	Wavelength	Total output
3D Printing	-	405 ~ 412 nm	-
Curing	60 minutes	415 ~ 420 nm	30 W

## 12. Finishing

Remove any support structures and finish jobs if necessary, using conventional dental methods and instruments. Differences in color may occur due to production in batches of the raw material and product or inadequate shacking of the original packaging before use.

## 13. Plastic and packaging waste

The product Tera Harz TC-85 in its polymerized form is not environmentally harmful. Residual waste material in its liquid state should be delivered to a collection point for waste material.

<b>Graphy</b>	IFU(Instructions For Use)	Sta No.	GRPIFU-002
		Rev Date	2022-06-30
	Tera Harz Clear TC-85 Resin for orthodontic devices	Rev No.	3
		Page	5/6

#### 14. Cleaning and disinfecting instructions

Graphy Inc. 3D-printing material should be cleaned with non chemical products. If disinfecting before intended use is required, an ethanol solution can be used.

#### 15. Shelf life

24 months from date of manufacture

#### 16. Manufacturer information

Manufacturer's name : Graphy Inc.

Location : #603, Ace Gasan Forhu, 225, Gasan digital 1-ro, Geumcheon-gu, Seoul,  
Republic of Korea

Contact: Mr. Tae-woo Kim / QMR

TEL. +82-2-864-3056

FAX. +82-2-864-3057

Homepage : [www.itgraphy.com](http://www.itgraphy.com)

#### 17. European Representative

Company name : S.B. PHARMA GMBH

Address : Bunsenstr. 14 53121 Bonn, Germany

Contact : Dr. Sina Seifi / Business development manager

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<b>Graphy</b>	IFU(Instructions For Use)	Sta No.	GRPIFU-002
		Rev Date	2022-06-30
	Tera Harz Clear TC-85 Resin for orthodontic devices	Rev No.	3
		Page	6/6

## 18. Delivery units

The product Tera Harz Clear is available in the following packaging size: 1000 g.

Explanation of symbols on labelling

Symbol	Definition	Symbol	Definition
	CE mark with NB number		Catalog number
	Batch number of product		Date of manufacture
	Use-by date		Consult instructions for use
	Caution		Non sterile
	Keep away from sunlight		Recycle
	Do not use if package is damaged		Fragile, handle carefully
	Upper and lower temperature limitation		Manufacturer
	Authorized Representative in the European Community		CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.