

**EC DECLARATION OF CONFORMITY**

(Manufacturer's Declaration)

This Declaration of Conformity is only valid with record of final inspection for a specific lot. / device enclosed.

**MANUFACTURER:**

Graphy Inc.  
1607 Gasan SK V1 Center, 171, Gasan digital 1-ro,  
Geumcheon-gu, Seoul, Republic of Korea  
TEL. +82-2-864-3056

**EUROPEAN REPRESENTATIVE:**

S.B. PHARMA GMBH  
Max-Planck Str., 39a D-50858, Koln, Germany  
Tel. +49 (0) 2234 988 1521

**COMMON/GENERIC NAME:**

Preformed Crown and Bridge

**TRADE/PROPRIETARY NAME:**

TERA HARZ

**MODEL/TYPE:**

TC-80DPA2, TC-80DPA3

**CLASSIFICATION:**

IIa

**RULE TO BE APPLIED:**

Rule 8

**CONFORMITY ASSESSMENT ROUT:**

Annex II (excluding section 4) (Full Quality Assurance),  
According to 93/42/EEC as amended by Council Directive  
2007/47/EC

*WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE PRODUCT CONCERNED HAS BEEN DESIGNED AND MANUFACTURED UNDER A QUALITY MANAGEMENT SYSTEM ACCORDING TO ANNEX II OF DIRECTIVE 93/42/EEC.*

**STANDARDS APPLIED:***Refer to the Attachment #1***NOTIFIED BODY:**

Notified Body Number 2764,  
Notice Belgelendirme, Muayene ve Denetim Hizmetleri  
Anonim Şirketi

**(EC) CERTIFICATE(S):**

CE-MDD-0093/04/2020/01

**ISSUED/EXPIRY DATE:**

27.04.2020 – 26.05.2024

**IDENTIFICATION NUMBER:**

Technical File (No. GRPTF-001, Rev 2)

**GMDN CODE:**

38781

**DATE OF ISSUE, IN PLACE:**

27/04/2020, Seoul,

**SIGNATURE:**

Mr. Un seob Sim / President  
On behalf of Graphy, Inc.



## **Attachment #1.**

### **European Norms and Standards and other Documents supporting Technical Files:**

Medical Devices Directive 93/42/EEC (as amended by Directive 2007/47/EC)

EN 1041:2008/A1:2013, Information supplied by the manufacturer of medical devices

EN 62366-1:2015, Medical devices – Part 1: Application of usability engineering to medical devices

EN ISO 7405:2018, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry

EN ISO 10477:2018, Dentistry – Polymer-based crown and veneering materials

EN ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing

EN ISO 10993-3:2014, Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

EN ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-6:2016, Biological evaluation of medical devices – Part 6: Tests for local effects after implantation

EN ISO 10993-10:2013, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

EN ISO 10993-11:2018, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

EN ISO 10993-12:2012, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

EN ISO 11607-1:2017, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

EN ISO 11607-2:2017, Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

EN ISO 13485:2016/AC:2018, Medical Devices – Quality Management Systems for Regulatory Purpose

EN ISO 14971:2012, Medical devices – Application of risk management to medical devices

EN ISO 15223-1:2016, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

MEDDEV 2.7/1 rev.4, Clinical evaluation: Guide for manufacturers and notified bodies

MEDDEV 2.12/1 rev.8, Guidelines on a medical devices vigilance system

MEDDEV 2.12/2 rev.2, Post market clinical follow-up studies