

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.
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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:

Orthodontic Preformed Direct Aligner

TRADE/PROPRIETARY NAME:

TERA HARZ CLEAR

MODEL/TYPE:

TC-85DAC, TC-85DAW

CLASSIFICATION:

IIa

RULE TO BE APPLIED:

Rule 5

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-002, Rev 2)

GMDN CODE:

16730

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 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

EN ISO 20795-1:2013, Dentistry - Base polymers - Part 1: Denture base polymers

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