Graphy

CE 2764

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. #603, #617, Ace Gasan Forhu, 225, Gasan digital 1-ro, Geumcheon-gu, Seoul, Republic of Korea TEL. +82-2-864-3056
SRN	KR-MF-000012692
EUROPEAN REPRESENTATIVE:	SMB Europe SAS 41, Ave de la République, 94300 Vincennes, France Tél : + 33 (6) 22 67 60 29 info@smbeurope.com
COMMON/GENERIC NAME:	Preformed Crown and Bridge
TRADE/PROPRIETARY NAME:	TERA HARZ
MODEL/TYPE:	TC-80DPA1, TC-80DPA2, TC-80DPA3, BR-23A1, BR-23A2, BR-23A3, BR-23B1, BR-23B2, BR-23B3, BR-23C1, BR-23C2, BR-23C3, BR-23D1, BR-23D2, BR-23D3, BR-23M4, BR-23OM1, BR-23OM2, BR-23OM3
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 11)
GMDN CODE:	38781
DATE OF ISSUE, IN PLACE:	10/12/2022, 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)
Medical Devices Regulation(EU) 2017/745

EN ISO 20417:2021, Information supplied by the manufacturer of medical devices
EN1641:2009, Dentistry – Medical devices for dentistry – Materials
EN 62366-1:2015/A1:2020, 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 10993-12:2021, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
EN ISO 10993-17:2009, Biological evaluation of medical devices - Part 17: Establishmentof allowable limits for leachable substances
EN ISO 10993-18:2020, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO/TS 21726 :2019 , Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
EN ISO 11607-1:2020, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems(ISO 11607-1: 2019)
EN ISO 11607-2:2020, 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 :2019, Medical devices – Application of risk management to medical devices
CEN ISO/TR 20416:, Medical devices – Post market surveillance for manufacturers (ISO/TR

20416:2020)

EN ISO 15223 -1:2021, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223 -1: 2021)

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

MDCG 2020-7, Post-market clinical follow-up (PMCF) Plan Template

MDCG 2020-8, Post-market clinical follow-up (PMCF) Evaluation Report Template

MDCG 2022-21, Guidance on Periodic Safety Update Report (PSUR)

Attachment #2 – UDI-DI

Model name	UDI-DI
TC-80DPA1	8800142100109
TC-80DPA2	8800142100116
TC-80DPA3	8800142100123
BR-23A1-500	8800142100604
BR-23A1-1000	8800142100604
BR-23A2-500	8800142100628
BR-23A2-1000	8800142100635
BR-23A3-500	8800142100642
BR-23A3-1000	8800142100659
BR-23B1-500	8800142100666
BR-23B1-1000	8800142100673
BR-23B2-500	8800142100680
BR-23B2-1000	8800142100697
BR-23B3-500	8800142100703
BR-23B3-1000	8800142100710
BR-23C1-500	8800142100727
BR-23C1-1000	8800142100734
BR-23C2-500	8800142100741
BR-23C2-1000	8800142100758
BR-23C3-500	8800142100765
BR-23C3-1000	8800142100772
BR-23D1-500	8800142100789
BR-23D1-1000	8800142100796
BR-23D2-500	8800142100802
BR-23D2-1000	8800142100819
BR-23D3-500	8800142100826
BR-23D3-1000	8800142100833
BR-23OM1-500	8800142100840
BR-23OM1-1000	8800142100857
BR-23OM2-500	8800142100864
BR-23OM2-1000	8800142100871
BR-23OM3-500	8800142100888
BR-23OM3-1000	8800142100895
BR-23M4-500	8800142100185
BR-23M4-1000	8800142100895