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7. EC Declaration of Conformity

(Rev. 4)

Product: Intra-oral Wound Dressing

(Model: OB23, OB53 and AD12)

	NAME / SIGNATURE	DATE
PREPARED BY:	Dong Kyun Yu / 유동균	2022.07.08
REVIEWED BY:	Dong Kyun Yu / 유동균	2022.07.08
APPROVED BY	Jae Woong Jung /	2022.07.08

TBM Corporation

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Document Revision History

Rev. No.	Date	Revision Clause	Revision Details	Approval	
0	2020-02-03	None	Initial release	Prepared by	(sign)
				Reviewed by	(sign)
				Approved by	(sign)
1	2021-05-20	All	Add brand name,	Prepared by	(sign)
				Reviewed by	(sign)
				Approved by	(sign)
2	2021-07-05	Page 3	SRN No. Update	Prepared by	(sign)
				Reviewed by	(sign)
				Approved by	(sign)
3	2022-01-11	Appendix I	Add of the Model (AD12) Revision of Reference Standard Revision of the GMDN Code as a EMDN Code according to launching EMDN Database	Prepared by	(sign)
				Reviewed by	(sign)
				Approved by	(sign)
4	2022-07-08		Change of EU Representative	Prepared by	Dong Kyun Yu (sign)
				Reviewed by	Dong Kyun Yu (sign)
				Approved by	Jae Woong Jung (sign)

EU DECLARATION OF CONFORMITY

Manufacturer:	**EU Representative:**
TBM Corporation. B-301, 313, Cheomdangwagi-ro, Buk-gu, Gwangju, 61008, Korea	KTR Europe GmbH Mergenthalerallee 77, 65760 Eschborn, Germany

Product Name	Intra-oral Wound Dressing
Brand Name	Ora-Aid
Model Name	OB23, OB53 and AD12
Intended Purpose	It is used to protect oral wound by forming a physical barrier on the wound.
EMDN Code	Q010304 (Periodontal Dressing)
SRN	KR-MF-000008542
EU Representative SRN	DE-AR-000005685
Basic UDI-DI	88000268AG9R
Classification	Class I (According to Rule 4 of (EU)2017/745, Annex VIII)
Reference to Technical Documentation	TF-000 (Rev.3)
Reference Standard (Including CS)	See the next pages (Appendix I)

We hereby declare that the device is in conformity with the (EU) 2017/745 and with any other relevant union legislation that provides for the issuing of an EU declaration of conformity.

CE

The above mentioned declaration of conformity is issued under the sole responsibility of TBM Corporation.

Gwangju, Korea 2022-07-08
Place, *date*

Name CEO **Jaewoong Jung**
Function, Legally binding signature

Appendix I. Reference Standards

- (EU)2017/745, Medical Device Regulation
- EN ISO 13485: 2016, Medical devices - Quality management systems – Requirements for regulatory purposes
- ISO 14971: 2019, Medical devices - Application of risk management to medical devices
- ISO/TR24971:2020, Medical Devices – Guidance on the application of ISO 14971
- ISO 15223-1:2021, Symbols for use in the labeling of medical devices
- ISO 20417: 2021, Information supplied by the manufacturer with medical devices
- EN 13726-1:2002, Test methods for primary wound dressings - Part 1: Aspects of absorbency
- EN 13726-2:2002, Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings
- EN 13726-4:2003, Test methods for primary wound dressings. Conformability
- EN ISO 10993-1:2020 (ISO 10993-1:2018), Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process
- EN ISO 10993-5:2009, Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices — Part 10: Tests for skin sensitization
- EN ISO 10993-23:2021 (ISO 10993-23:2021), Biological evaluation of medical devices — Part 23: Tests for irritation
- IEC 62366-1:2015/AMD1:2020, Medical devices - Part 1: Application of usability engineering to medical devices
- KP 11th Edition: 2016, THE KOREAN PHARAMACOPOEIA ELEVENTH EDITION
- ASTM 1980:2016, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F 88 / F88M:2015, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F 1929:2015, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- MEDDEV 2.7.1, Rev 4, Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies
- MEDDEV 2.12-1, Rev 8, GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM

MDCG Guidance

1) UDI Guidance

- MDCG 2018-1 v4, Guidance on basic UDI-DI and changes to UDI-DI
- MDCG 2018-2, Future EU medical device nomenclature - Description of requirements
- MDCG 2018-6, Clarifications of UDI related responsibilities in relation to article 16
- MDCG 2018-7, Provisional considerations regarding language issues associated with the UDI database
- MDCG 2019-1, MDCG guiding principles for issuing entities rules on basic UDI-DI
- MDCG 2021-19, Guidance note integration of the UDI within an organisation's quality management system

2) EUAMDE Guidance

- MDCG 2018-7, Provisional considerations regarding language issues associated with the UDI database
- MDCG 2019-5, Registration of legacy devices in EUDAMED

3) Clinical Evaluation Guidance

- MDCG 2020-13, Clinical evaluation assessment report template
- MDCG 2020-8, Guidance on PMCF evaluation report template
- MDCG 2020-7, Guidance on PMCF plan template
- MDCG 2020-6, Guidance on sufficient clinical evidence for legacy devices
- MDCG 2020-5, Guidance on clinical evaluation – Equivalence

4) EMDN Guidance

- The EMND-The nomenclature o fuse in EUDAMED
- MDCG 2021-12, FAQ on the European Medical Device Nomenclature (EMDN)

5) Classification

- MDCG 2021-24, Guidance on classification of medical devices

6) Standards

- MDCG 2021-5, Guidance on standardisation for medical devices