EC DECLARATION OF CONFORMITY

Manufacturer

HULASER, Inc.
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EU Representative

KTR Europe GmbH
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- **Product:** Dental Diode Laser
- **Models:** K2 MOBILE, K2 FINGER
- **GMDN Code:** 15757
- **Classification:** IIb (According to Rule 9 of 93/42/EEC+2007/47/EC, Annex IX)
- **Reference to Technical Documentation:** HU-TCF-004
- **Reference Standard:** See the next pages (Appendix I)
- **EC certificate No.:** IT270244-2 (expiring date: 26 May, 2024)

We hereby declare that the product meets the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC. The product has been designed and manufactured under a quality management system according to Annex II (excluding Section 4) of Directive 93/42/EEC as amended by 2007/47/EC.

Compliance of the designated product with the Directive 93/42/EEC as amended 2007/47/EC has been assessed and certified by the Notified Body

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The above mentioned declaration of conformity is exclusively under the responsibility of HULASER, Inc.

Seoul, Korea,	2020-01-30	Park, Inbae
Place,	*date*	*Legally binding signature, Function*

Appendix I. Reference Standards

No.	Standard or Guidance	Title
1	ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2012 (ISO 14971:2007)	Medical devices - Application of risk management to medical devices
3	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
4	EN 1041: 2008	Information supplied by the manufacturer of medical devices
5	IEC 60601-1:2005+A1: 2012 (EN 60601-1:2006+A1: 2013) (AAMI/ANSI ES 60601-1: 2005+A1: 2012)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
6	IEC 60601-1-2:2014 (EN 60601-1-2:2015)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility Requirements and tests.
7	IEC 60601-1-6:2010+A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
8	IEC 60601-2-22:2007+A1:2012	Medical electrical equipment. Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
9	IEC 60825-1: 2014 (EN 60825-1: 2014)	Safety of laser products - Part 1: Equipment classification and requirements
10	IEC 62133: 2012 (EN 62133:2013)	Secondary cells and batteries containing alkaline or other non-acid electrolytes. Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
11	IEC 62366:2007 (EN 62366:2008)	Medical devices – Application of usability engineering to medical devices.
12	IEC 62304:2006	Medical device software - Software life cycle processes

	(EN 62304:2006)	
13	ISO 10993-1:2018 (EN ISO 10993-1:2018)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
14	ISO 10993-5:2009 (EN ISO 10993-5:2009)	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
15	ISO 10993-10:2010 (EN ISO 10993-10:2013)	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
16	ISO 10993-12:2012 (EN ISO 10993-12: 2012)	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
17	EN ISO 17664:2017 (ISO 17664: 2017)	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
18	MEDDEV 2.7.1, Rev 4	Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies