# *EC DECLARATION OF CONFORMITY*

**Manufacturer**

HULASER, Inc.
1110, Daerung Technotown 17, 25, Gasan digital 1-ro,
Geumcheon-gu, Seoul 08594, Korea

**EU Representative**

KTR Europe GmbH
Mergenthalerallee 77, 65760,
Eschborn Germany

- **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

**BUREAU VERITAS ITALIA S.P.A.**

Viale Monza, 347 – 20126 MILANO (MI), Italy

CE 1370

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

| Seoul, Korea, | 2021-05-24 | 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<br>(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<br>(EN 60601-1:2006+A1: 2013)<br>(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<br>(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<br>(EN 60825-1: 2014) | Safety of laser products - Part 1: Equipment classification and requirements |
| 10 | IEC 62133: 2012<br>(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<br>(EN 62366:2008) | Medical devices – Application of usability engineering to medical devices. |

| | | |
|---|---|---|
| 12 | IEC 62304:2006<br>(EN 62304:2006) | Medical device software - Software life cycle processes |
| 13 | ISO 10993-1:2018<br>(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<br>(EN ISO 10993-5:2009) | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity |
| 15 | ISO 10993-10:2010<br>(EN ISO 10993-10:2013) | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization |
| 16 | ISO 10993-12:2012<br>(EN ISO 10993-12: 2012) | Biological evaluation of medical devices - Part 12: Sample preparation and reference materials |
| 17 | EN ISO 17664:2017<br>(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 |