June 10th , 2024

C/0450/24/GF/mab

To: **HULASER, Inc.**
1110, DAERUNG TECHNOTOWN 17, 25, GASAN DIGITAL 1-RO,
GEUMCHEON-GU
08594 SEOUL - KOREA

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate **N° IT270244 – 2**
Directive 93/42/EEC (MDD)

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement n. 22457669 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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Table n.1

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**Device name under MDD corresponding to the device under MDR application**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application**
Active dental devices (K2 Mobile, K2 Finger)	IIb	Active dental devices Dental diode laser K2 Mobile, K2 Finger	Certificate N° IT270244 – 2 issued on 2020/02/20

In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

a. The above-mentioned agreement n° 22457669 was signed within 2024/09/26.
b. Bureau Veritas Italia Spa is responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which

an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1

As required by EU Regulation 2023/607, the validity of the MDD certificate: N° IT270244 – 2 is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

Confirmation Letter Revision History

Date	Revision	Action
2024/05/31	0	Initial issue



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Soggetta all'attività di direzione e coordinamento da parte di Bureau Veritas SA con sede in Neuilly-sur-Seine - Francia

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