



May 22nd , 2024

C/0362/24/GF/vc

To: ZAMAR MEDICAL d.o.o.
Sv. MARTIN, 6
52450 – VRSAR (PU - CROAZIA)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking **Certificate n° MED 25026 rev.6 - 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. 5489301 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

ZAMAR MEDICAL d.o.o.
Sv. MARTIN, 6
52450 – VRSAR
CROAZIA

Tabella 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
ZT CUBE ZT CLINIC ZCCAREPACE Z-ONE ZHC	Ila	ZTCube; ZTClinic; ZCCarepace; Z-ONE; ZHC.	Certificate n° IT256270- 2 issued on 2021/05/25

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

- The above-mentioned agreement n. 5489301 was signed within 2024/09/26.
- 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° IT256270- 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
2024/05/22	0	Initial issue


GLORIA FOCETOLA - Local Technical Manager