



June 10th , 2024

C/0437/24/GF/vc

To: **TESLA MEDICAL S.R.L**
Via Guglielmo Melisurgo, 44
80133 - NAPOLI (NA)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate **N° IT306205 - 1**
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. 4758173 rev.2, in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

TESLA MEDICAL S.R.L
Via Guglielmo Melisurgo, 44
80133 - NAPOLI (NA)
ITALY

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
OSTEOPLUS BIOSTIMOLATORE TISSUTALE	Ila	OSTEOPLUS	Certificate N° IT306205-1 on 2021/05/06



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° 4758173 rev.2 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° IT306205 - 1 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
2024/06/10	0	Initial issue


GLORIA FOCETOLA - Local Technical Manager