



February 19, 2024

C/0121/24/GF/mab

To: BIOMEDICAL SRL
Via Giambattista Lulli, 43
50144 – Firenze (FI)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate n° **0068/QCO-DM/404-2021 – 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.4585918, in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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50144 – Firenze (FI)
Italy

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
TATO2, TATO3	I Ib	TATO2, TATO3	Certificate n°. 0068/QCO-DM/404-2021, issued on 25/05/2021
TATOPro	I Ia	TATOPro	Certificate n°. 0068/QCO-DM/404-2021, issued on 25/05/2021

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. 4585918 was signed within 2024/09/26;
- Bureau Veritas Italia Spa is not 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° MED 26036 rev.23, 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
2024/02/19	0	Initial issue

- Local Technical Manager