



Milan, June 12th 2023
C/0332/23/GL/mab

To: SIMPLE & SMART SRL
Via Perola 16, 24021 ALBINO (BG)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate n. **IT261641-3 – Directive 93/42/EEC (MDD) – 9405369**

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. 4568763) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SIMPLE & SMART SRL
Via Perola 16, 24021
ALBINO (BG)
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
SS_ONE SS_KISS SS_ITALO	Ila	SS_ONE SS_KISS SS_ITALO	Certificate IT261641-3 issued on 11/05/2021

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. 4568763) was signed before the expiry date (2023/07/02) of the certificate shown in table n.1;
- 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. IT261641-3 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
2023/06/12	0	Initial issue

GIORGIO LANZAFAME
Bureau Veritas Italia S.p.A.
Certification Division
LOCAL TECHNICAL
MANAGER