



June 4th , 2024

C/0422/24/GF/mab

To: **ASSING S.p.A.**

Via E. Amaldi, 14

00015 - MONTEROTONDO (RM)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate **N° IT272133 - 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. 4494837 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

ASSING S.p.A.

Via E. Amaldi, 14

00015 - MONTEROTONDO (RM)

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 |
|--|--|--|--|
| HELIOS DRF | IIB | HELIOS DRF | Certificate n° IT272133 - 1 issued on 2020/07/28 |

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° 4494837 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° IT272133 - 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 |
|------------|----------|---------------|
| 2024/06/04 | 0 | Initial issue |



GLORIA FOCETOLA - Local Technical Manager