CE 1639

CE – DECLARATION OF CONFORMITY

OLIN-1

We declare that the following medical device complies with the National Law transposing Council Regulation Directive 93/42/EEC of 14 June 1993 on medical devices. All relevant documentation is maintained at the manufacturer's premises.

- **Manufacturer:** ENELINI ASSOCIATS, S.L.U.

  C/ Llull, 88 Local 2 - 08005 Barcelona - Spain - Phone +34 931 620 357

- **Product description:** Sterile and single use OLIN-1 Kit (20 ml and 40 ml), consisting of 4 types of syringes, adapter, and stopper, for the collection of blood cells for PRP treatment of musculoskeletal disorders.
- **Product name:** OLIN-1 KIT.
- **Classification:** Class ***IIa*** sterile according rule 2 of Annex IX of Directive.
- **Directives:** Directive 93/42/EEC relative to Medical Devices.
- **Date:** 20/12/2019
- **Standards:**
  - ✓ RD 1591/2009 relative to Medical Devices.
  - ✓ UNE-EN ISO 13485:2018 Medical Devices – Quality Management Systems. Requirements for regulatory purposes.
  - ✓ UNE-EN ISO 14971:2020 Medical Devices – Application of risk management to medical devices.
  - ✓ UNE-EN ISO 10993-1:2010 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
  - ✓ UNE EN ISO 15223-1:2017 Medical devices: Symbols to be used with medical Device labels, labelling and information to be supplied. Part 1: General requirements.

This declaration of conformity is supported by the internal SOP_35 (Procedure of Conformity Evaluation) and Certificate number ES16/19753 on Quality Assurance in accordance with Annex II to Directive 93/42/EEC issued on 09 April 2021 by SGS – BELGIUM, Notified Body Nº. 1639.

Responsible Person and Responsibility: Enric Jordà Ventosa, CEO.

Signature: