EC Certificate Full Quality Assurance System: Certificate ES19/86945

The management system of

Enelini Associats, S.L.U.

C/ Llull, 88, 08005 Barcelona. Spain

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile and single use OLIN-1 kit (20ml and 40ml), consisting of 4 types of syringes, adapter and stopper, for the collection of blood cells for PRP treatment of musculoskeletal disorders.

Kit OLIN-1 (20ml y 40ml) estéril y de un solo uso, compuesto por 4 tipos de jeringas, adaptador y tapón, para la recolección de células sanguíneas con fines de tratamientos de desordenes músculo esqueléticos mediante PRP.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 09 April 2021 until 10 April 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 04 October 2016

Certification is based on reports numbered ES/BCN 210014

Authorised by

Global Medical Devices Head of Notified Body

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