Certificate ES16/19753

The management system of

Enelini Associats, S.L.U.

C/ Llull 88, local 2, 08005 Barcelona. Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2016/EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities
Design, Manufacture, Sales and Distribution of Sterile disposable syringes for collection of blood cells for PRP treatment of musculoskeletal disorders.
Distribution of Sterile Non-active Implantable Devices.
Distribution of sterile non-active non-implantable medical device kits for the collection of blood cells.

Diseño, fabricación, venta y distribución de jeringas desechables estériles para la recolección de células sanguíneas con fines de tratamientos de desórdenes músculo esqueléticos mediante PRP.
Distribución e importación de Productos Implantables no Activos Estériles.
Distribución de kits de dispositivos médicos estériles, no implantables, no activos para la recolección de células sanguíneas.

This certificate is valid from 30 January 2026 until 08 April 2027 and remains valid subject to satisfactory surveillance audits.
Issue 9. Certified since 11 April 2016

L. Moran

Authorised by
Liz Moran
Business Manager

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