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

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

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.
Distribuición de Productos Implantables no Activos Estériles

This certificate is valid from 09 July 2024 until 08 April 2027 and remains valid subject to satisfactory surveillance audits.
Issue 8. Certified since 11 April 2016

Last certificate expiry date 08 April 2027
Recertification audit date 13 February 2024

Authorised by
Jonathan Hall
Global Head - Certification Services

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

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

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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ENELINI ASSOCIATS, S.L.U.
C/ Llull 88, local 2, 08005, Barcelona, Spain

Sept 10h, 2024

Confirmation Letter Reference: CLNB1639 - ES/BCN/210014

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer

ENELINI ASSOCIATS, S.L.U.
C/ Llull 88, **local 2,** 08005, Barcelona, Spain
SRN Number: ES-MF-000009466

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,

Ian How
PP

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**:**

Device name or Basic UDI-DI	**MDR Device classification**	**MDD Device name**	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Kit OLIN-1® Sterile and single-use syringes, adapter, and stopper, for the collection of blood cells for PRP treatment of musculoskeletal disorders. Basic UDI-DI: 8437018288OLIN-1FA	Class IIa	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.	N/A	Certificate #1 ES19/86945; NB1639

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
N/A: NB1639 is responsible for all SUR visit under directive	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/18	Version 1	Initial issue
2024/09/10	Version 2	Amend address to include “local 2” in it. Previous address: C/ Llull, 88. 08005, Barcelona, Spain Amended address: C/ Llull 88, local 2, 08005, Barcelona, Spain