

Certificate ES13/13505

The management system of

MONLAB, S.L.

C/ Selva de Mar 48 08019 Barcelona, Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 January 2016 until 23 January 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 January 2019

Issue 2. Certified since 24 January 2013

Authorised by

SGS United Kingdom Ltd Systems & Services Certification Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK t+44 (0)151 350-6666 f+44 (0)151 350-6600 www.sgs.com

SGS 13485-2 0614 M2

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Certificate ES13/13505, continued

MONLAB, S.L.

ISO 13485:2003 EN ISO 13485:2012



Issue 2

Detailed scope

Manufacture, importation, marketing and distribution of IVD kits, consumables and reagents for clinical diagnostic and analytical

Marketing, distribution and technical support for equipment and automated systems for clinical diagnostic and testing laboratories.

Fabricación, importación, comercialización y distribución de kits IVD, fungibles y reactivos para diagnósticos clínicos.

Comercialización, distribución y asistencia técnica de equipos y sistemas automáticos para laboratorios de diagnóstico clínico y ensayo.

