

This is a translation of the certificate ES16/20725.01



DELTALAB, S.L.

Pol.Ind. La Llana, Plaza de la Verneda, 1, 08191 Rubí, Barcelona

Has been assessed under the management system of the certified organisation defined in the main certificate ES16/20725 as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, hematology, biochemistry, histology, microscopy and colorimetric analysis.

Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.

Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products and cosmetics.

This certificate is valid from 11 October 2022 until 11 October 2025 and remains valid subject to satisfactory surveillance audits.

Issue 2.

The validity of this certificate depends on the validity of the main certificate.

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Detalab, S.L. defines and makes public its commitment with the Standard ISO 9001:2015 Quality Management Systems, ISO 14001:2015 Environmental Management Systems and ISO 13485:2016 Medical devices – Quality Management Systems, with the aim to create value and satisfy all its interested parties:

- Shareholders
- Members of the organisation
- Customers and suppliers
- All members of the surrounding community

The development of this Integrated Management System Policy is carried out with the philosophy of Continuous Improvement and with the support of all the processes described in our Integrated Management System, in order to achieve the following objectives:

1. Become leaders in the design and manufacture of single use products for the laboratory.
2. Bring solutions to cover the current and future customer needs, related to:
 - Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiology, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis.
 - Design, manufacture and sale of sterile and non-sterile medical devices for the collection, transport and conservation of biological samples for clinical and *In Vitro Diagnostic analysis*.
 - Commercialization of diagnosis reagents, equipment and instrumentation for laboratory and equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.
 - Commercialization of personal care, cosmetics and dietetic products
3. Maintain a constant growth, both in local and international markets, by means of mergers, acquisitions and by launching new products.
4. Achieve the full satisfaction of our customers, by means of a strict compliance to the agreements and expectations agreed with them, as well as the excellence in the service.
5. Reach a high level of innovation of our products and processes, in cooperation with universities, research centers, key opinion leaders and experts, both local and international.
6. Fulfil the legislation and regulatory requirements applicable to the activities carried out by the company, including those applicable to the quality of products and the environmental management.
7. *Fulfil the regulations applicable to the commercialized products, including the European Directives 93/42/CEE and 98/79/CE, Regulations (UE) 2017/745 and 2017/746 and Spanish Royal Decrees 192/2023 and 1662/2000, on medical devices and in vitro diagnostics medical devices respectively.*
8. Commit ourselves with the environmental protection, including the prevention of pollution.
9. Achieve and keep a high motivation and involvement of all members of the organisation, suppliers, distributors and customers, by fulfilling the highest Quality and environmental protection standards.
10. Improve the working conditions of all employees and ensure the technical capacity of the personnel by giving them the adequate training with the aim to achieve the required competence.
11. Establish a close relationship with the suppliers and guarantee the maximum quality of materials supplied by means of quality agreements.

The Integrated Management System is periodically reviewed to define the required actions to ensure that:

- ✓ The System is efficient, so that it is a tool for the routine of all the members of the organisation.
- ✓ The customer needs and requirements are duly identified, and their expectations are always met.
- ✓ All members of the organisation are familiar with and know the objectives and policy of the Integrated Management System, and that adequate training plans are defined to achieve them.
- ✓ Encourage the Continuous Improvement Philosophy, both related to Quality and Environmental Management.

This Policy is made available for the public and all interested parties.

Dr. Pongsuda Pongtanya
Managing Director
17th May 2024

Certificate ES10/81671

The management system of

DELTALAB, S.L.

Polígono Industrial La Llana, Plaza de la Verneda 1, 08191 Rubí, 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 and sale of sterile and non-sterile medical devices for the collection, transport and conservation of biological samples for clinical and IVD analysis.

Distribution of non-active medical devices and in vitro diagnostic medical devices.

Diseño, fabricación y comercialización de productos sanitarios estériles y no estériles para la toma, transporte y conservación de muestras biológicas para análisis clínicos y de IVD.

Distribución de productos sanitarios no activos y productos sanitarios para diagnóstico in vitro.

Disseny, fabricació i comercialització de productes sanitaris estèrils i no estèrils per a la presa, transport i conservació de mostres biològiques per a anàlisis clíniques i de IVD.

Distribució de productes sanitaris no actius i productes sanitaris per a diagnòstic in vitro.

This certificate is valid from 12 October 2022 until 11 October 2025 and remains valid subject to satisfactory surveillance audits.

Issue 10. Certified since 12 October 2010.

Jonathan M. Hall

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Global Head - Certification Services

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