EC Certificate Full Quality Assurance System: Certificate ES10/82099

The management system of

Técnicas Científicas para Laboratorio, S.A.

C/ Lope de Vega, 99 - 101, 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

Sweat Chloride analyzer for the diagnosis of cystic fibrosis ISEsweat II.

***Analizador de Cloruro en sudor* ISEsweat I y ISEsweat II**
para diagnóstico de la fibrosis quística.

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 17 February 2017 until 20 December 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 October 2019
Issue 5. Certified since 21 December 2010

Certification is based on reports numbered ES/BCN 150426

Authorised by

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