This is a translation of the certificate ES21/210073

The management system of



ASOCIACIÓN CENTRO DE INVESTIGACIÓN COOPERATIVA EN BIOCIENCIAS – CIC bioGUNE

Parque Científico Tecnológico de Bizkaia, Edificio 801-A, 48160 Derio, Bizkaia has been assessed and certified as meeting the requirements of

ISO 13485:2016

For the following activities

Design, development and manufacture of software to aid in the diagnosis of newborn congenital metabolic errors.

This certificate is valid from 30 July 2024 until 30 July 2027 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 30 July 2021

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by Certification Management

SGS International Certification Services Iberica, S.A.U. C/Trespaderne, 29. 28042 Madrid. España t +34 91 313 8115 - www.sgs.com





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Issue 2

Sites

ASOCIACIÓN CENTRO DE INVESTIGACIÓN COOPERATIVA EN BIOCIENCIAS – CIC bioGUNE Parque Científico Tecnológico de Bizkaia, Edificio 801-A, 48160 Derio, Bizkaia

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