





Certificate

No. Q5 115771 0001 Rev. 01

Holder of Certificate: Life Technologies Corporation

7335 Executive Way Frederick MD 21704

USA

Certification Mark:



Design and Development, Production and Distribution Scope of Certificate:

> of in vitro diagnostic software workflows, used to qualitatively determine the genome aneuploidies, including the trisomy status of Chromosome 21.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 115771 0001 Rev. 01

Report No.: 72196478 - MD

Valid from: 2024-09-13 Valid until: 2027-09-12

2024-09-13

Christoph Dicks

Head of Certification/Notified Body

Date.



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Applied Standard(s): ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Life Technologies Corporation

7335 Executive Way, Frederick MD 21704, USA

Top management

Life Technologies Corporation

7305 Executive Way, Frederick MD 21704, USA

Design and Development, Production and Distribution of in vitro diagnostic software workflows, used to qualitatively determine the genome aneuploidies, including the trisomy status of Chromosome

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