

JCB F 12.03 2012-02



CERTIFICATE

The Certification Body of TÜV SÜD AMERICA INC.

hereby certifies that

Dionex Softron GmbH, a part of Thermo Fisher Scientific

Dornierstrasse 4 Germering, BY 82110 Germany

(see page 2 for additional locations)

Has implemented a Quality Management System in accordance with:

ISO 13485:2016

The scope of this Quality Management System includes:

Design and Development, Contract Development, Manufacturing, Servicing and Technical Support of Chromatography Systems and Spares for In Vitro Diagnostic Applications

Certificate Expiry Date: March 5, 2021

Certificate Registration No: 951 20 5232

Issue Date: March 6, 2018 (From Previous Registrar)

Reissue Date: October 30, 2020



Vice President, Business Assurance







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CERTIFICATE

Dionex Softron GmbH, a part of Thermo Fisher Scientific

Dornierstrasse 4 Germering, BY 82110 Germany

Scope - Design and Development, Contract Development, Manufacturing, Servicing and Technical Support of Chromatography Systems and Spares for In Vitro Diagnostic Applications

Dionex Softron GmbH, a part of Thermo Fisher Scientific

Gewerbering 14a Olching-Geiselbullach, 82140 Germany

Scope - Design and Development, Contract Development, Manufacturing, Servicing and Technical Support of Chromatography Systems and Spares for In Vitro Diagnostic Applications

Processes - Supply Chain Activities: Goods Receipt and Incoming Inspection, Storage and Distribution of Finished Goods, Purchasing, and Sales Order Processing

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Mark Alpert Vice President, Business Assurance





