CERTIFICATE

This is to certify that the company

ORGENTEC Diagnostika GmbH

Carl-Zeiss-Straße 49 - 51
55129 Mainz
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design, development, manufacturing and distribution of in-vitro diagnostic medical devices and in-vitro diagnostic analyzers used in the diagnosis of autoimmune diseases comprising rheumatology, thrombosis, ANCA/vasculitis, thyroid, gastroenterology, diabetes diagnosis and infections diseases

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2003

Certificate registration No.	014965 MP23CMDR
Certificate unique ID	170593800
Effective date	2014-08-16
Expiry date	2017-08-15
Frankfurt am Main	2014-07-14

SCC Accredited CB-MS
OCSM Accrédité CCN

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DQS Medizinprodukte GmbH is a CMDCAS recognized registrar (Canadian Medical Devices Conformity Assessment System).

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