

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Diagnostic Automation/
Cortez Diagnostics, Inc.
21250 Califa St., Suite 102
Woodland Hills
California
91367
USA

Holds Certificate No:

FM 83092

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Manufacture and distribution of Elisa Kits (Autoimmune Diseases, Cancer Markers, Cardiac Markers, Allergy, Anemia, Fertility, Bone Metabolism, Steroids, Thyroid, Infectious Disease, Parasitology Antibody Detection, Parasitology Antigen Detection, Diabetes and Pancreatic Disease Assay, FOOD), Rapid Test Products, IFA Kits, Chemiluminescence Immuno Assays, Serology Test Kits and Instrumentation.

This certificate is traceable to this company's original registration certificate No. 751-03-01 dated 03/28/2003 and issued by Orion Registrar, Inc.

For and on behalf of BSI:

Reg Blake, VP Regulatory Affairs, BSI Group America Inc.

Original Registration Date: 04/09/2004

Effective Date: 12/22/2015

Expiry Date: 12/21/2018



CMDCAS
Recognized
Registrar



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