

Certificate

Quality Management System EN ISO 13485:2016

Registration No.:

SX 1243914-1

Organization:

DRG International., Inc. 841 Mountain Avenue Springfield NJ 07081

USA

Scope:

Manufacturing and distribution of in vitro diagnostic reagents used in the diagnosis of autoimmune status, cancer, cardiac markers, disease status, fertility testing, pregnancy testing, diabetes and immune status.

Installation and service of in vitro diagnostic analyzers.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality

management system is subject to yearly surveillance.

Report No.: 1120128-10
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Deutsche Akkreditierungsstelle D-ZM-14169-01-02