Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 1243914-1
Certificate Holder:	DRG International., Inc. 841 Mountain Avenue Springfield NJ 07081 USA
Scope:	Design and development, manufacture and distribution of in-vitro diagnostic test kits used in the diagnosis or detection of transmissible agents and sexually transmissible agents, cancer, prenatal screening, immune status, disease status, autoimmune status, drugs of abuse, cardiac markers, cardiovascular disease, endocrine disorders, fertility testing, pregnancy testing and the design and development, 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.:	1194196 -100
Effective date:	2025-11-02
Expiry date:	2028-11-01
Issue date:	2025-10-23

Replaces certificate SX 1243914-1 issued 2022-10-28

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This certificate can be validated on https://www.certipedia.com

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