CERTIFICATE OF REGISTRATION

Dako North America, Inc.

6392 Via Real
Carpinteria, CA 93013 United States

D-U-N-S ID No.099999732

UL Medical Regulatory Services of UL LLC® (UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

The design, manufacture and service of in-vitro diagnostic test kits, reagents, automated slide strainers and cellular imaging systems used in the diagnosis and/or management of cancer, immune status, disease status, autoimmune status, blood analytes, immunological typing and disease management.

With additional locations listed on Addendum 1 of 1

File Number	A12643	Cycle Start Date	January 28, 2018
		Effective Date	January 28, 2018
Certificate No.	11965795.AZBA	Expiry Date	January 27, 2021

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Medical and Regulatory Services
UL LLC

Validate Certificate:
here

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC.
Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL Medical and Regulatory Services of UL LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

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Addendum 1 of 1

Manufacturing Site 1 located at: **1170 Mark Ave.**
Carpinteria, CA 93013 United States
D-U-N-S ID No. 014883231

Performing: Manufacturing, quality assurance, sales, training, technical support, servicing and administration.

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Additional Regulatory Requirements

Australia:
- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure];

Brazil:
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada:
- Medical Devices Regulations – Part 1- SOR 98/282

Japan:
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (,as applicable)

United States:
- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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