



# CERTIFICATE OF REGISTRATION

## Dako Denmark ApS

Produktionsvej 42  
Glostrup DK-2600 DENMARK

REPs Facility ID: F001394

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, development and manufacture of antibodies, reagents and kits for in vitro diagnostics and research used in diagnosis and management of cancer, genetic testing, immune status, disease status, autoimmune status, protein metabolism, blood analytes, coagulation, transmissible agents, sexually transmissible agents and for immunological typing. The design, development, manufacture, installation and service of in vitro diagnostic instruments and software used in the diagnosis and management of cancer, genetic testing, immune status, disease status, autoimmune status, protein metabolism, blood analytes, coagulation, transmissible agents, sexually transmissible agents and for immunological typing.



Authorized by



Check Certificate  
Status: [here](#)

**Michael J. Windler, P.E.**  
Manager of Global Regulatory Service  
Distinguished Member of the Technical Staff  
UL Life and Health Sciences  
UL LLC

File Number	A12312	Cycle Start Date	July 7, 2018
Certificate Number	1690.191205	Effective Date	December 5, 2019
Initial Issue Date	July 7, 2018	Expiry Date	July 6, 2021

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 UL, LLC is an MDSAP  
Recognized Auditing  
Organization**

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



## Dako Denmark ApS

Produktionsvej 42  
Glostrup DK-2600 DENMARK

REPs Facility ID: **F001394**

### 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)

File Number	A12312	Cycle Start Date	July 7, 2018
Certificate Number	1690.191205	Effective Date	December 5, 2019
Initial Issue Date	July 7, 2018	Expiry Date	July 6, 2021

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 UL, LLC is an MDSAP  
Recognized Auditing  
Organization**

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