

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Immudex ApS  
Bredevej 2A  
2830 Virum  
Denmark

Holds Certificate Number:

**MD 724382**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of in vitro diagnostic tests using major histocompatibility complex (MHC) reagents and kits for detection of cytotoxic T-cells by flow cytometry within immuno-oncology, transplantation, autoimmunity and infectious disease.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-03-16

Latest Revision Date: 2022-03-16

Effective Date: 2022-03-16

Expiry Date: 2025-03-15



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