

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

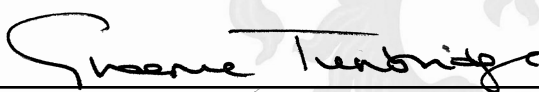
Holds Certificate Number:

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 Global Regulatory & Quality

Original Registration Date: 2022-03-16

Latest Revision Date: 2025-03-07

Effective Date: 2025-03-16

Expiry Date: 2028-03-15

Page: 1 of 1



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