

Certificate of Registration

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

This is to certify that:

Kreatech Biotechnology B.V.
Vlierweg 20
1032 LG Amsterdam
The Netherlands

Holds Certificate Number:

MD 724144

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

The design, development, manufacture and distribution of molecular biology based In Vitro Diagnostics devices, reagents, test kits and consumables for genetic testing used in the monitoring, prognosis and diagnosis of: cancer, transmissible agents and constitutional disorders.

Transfer from DEKRA
Certificate number: 2110388

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-07-10

Latest Revision Date: 2020-07-10

Effective Date: 2020-07-10

Expiry Date: 2021-12-01

Page: 1 of 1



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