

Certificate of Registration

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

This is to certify that:

BioGX B.V.
Science Park 408
Suite #2.08
Amsterdam
1098 XH
The Netherlands

Holds Certificate Number:

MD 685785

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 in-vitro diagnostic kits, reagents and kit components for use in molecular diagnostics.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-05-23

Latest Revision Date: 2019-05-23

Effective Date: 2019-05-23

Expiry Date: 2022-05-22

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