

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LinguaFlex, Inc.
322 North Shore Drive, Suite 200
Pittsburgh
Pennsylvania
15212
USA

Holds Certificate No:

FM 591440

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

Design and Development and Manufacture Non-sterile medical devices and associated surgical instruments to treat sleep apnea.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-02-13

Latest Revision Date: 2019-01-31

Effective Date: 2019-02-13

Expiry Date: 2022-02-12

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