



Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number:

MD 592406

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 and control of manufacture of non-sterile tongue retractor device and associated surgical instruments for the treatment of obstructive sleep apnea.

Previous certificate expired on 2019-02-12 Recertification audit ended 2018-11-01

JM SI

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2013-03-07 Latest Revision Date: 2019-03-06 Effective Date: 2019-03-06 Expiry Date: 2022-02-12

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory

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