

# 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



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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