

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

USA

Great Lakes NeuroTechnologies Inc. 10055 Sweet Valley Drive Suite 1 Cleveland Ohio 44125

Holds Certificate No: FM 575143

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

Design, manufacture and distribution of wireless patient monitoring devices for movement disorders.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally Registered: 11/07/2011 Effective Date: 05/04/2012 Expiry Date: 11/06/2014



CMDCAS Recognized Registrar



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