

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: ATL Technology DG Limited
Kang Le Road
Xitou Village Houjie Town
Dongguan City
Guangdong
523952
China

东莞亨丰电子有限公司
914419005626351048
中国
广东省
东莞市
厚街镇溪头村
康乐路
邮编: 523952

Holds Certificate No: **MD 642005**

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

Contractually specified manufacturing of devices, components and accessories for the medical device industry, including cutter driver for directional atherectomy systems, ablation systems, electrode assemblies, air/oxygen tubing assemblies, hospital support clamps, pipettes, cables and connectors.

医疗器械行业合约规定的器械, 部件与附件的制造, 包括: 定向经皮腔内斑块旋切术系统用驱动手柄, 消融系统、电极组件、空气/氧气管组件、医疗用固定夹、吸管、电缆及连接器。

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2015-05-05

Latest Revision Date: 2018-05-03

Effective Date: 2018-05-05

Expiry Date: 2021-05-04



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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 [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.