

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Applied Medical Technology, Inc.

(FIN F000737)

Main Site: 8006 Katherine Boulevard, Brecksville, Ohio 44141 United States

Additional Site: 8000 Katherine Boulevard, Brecksville, Ohio 44141 United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

The design, manufacture and distribution of enteral feeding devices, balloon stoma measuring devices, enteral feeding device accessories, initial placement gastrointestinal kits, self-retaining retractor systems, smoke evacuators, bowel management systems and breast implant removal devices.

Certificate Number:

0074621-05

Initial Certification Date:

2018-04-23

Certificate Effective Date:

2021-04-22

Certificate Expiry Date:

2022-04-22



Intertek

Calin Moldoveanu

President, Business Assurance

Intertek Testing Services NA, Inc.
900 Chelmsford Street
Lowell, MA, USA 01851

