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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Black Tie Medical, Inc. dba Tulip Medical Products

(F004127)

Main Site: 4360 Morena Blvd., Suite 100, San Diego, California, 92117,

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

- Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable)

- United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D), 21 CFR 821

The management system is applicable to:

Design and development, production and distribution of Liposuction, Fat-Harvesting, Tissue-Harvesting, Fluid and Tissue Injection Systems and Accessories.

Certificate Number:
0102982

Initial Certification Date:
2020-07-01

Certification Effective Date:
2020-07-01

Certification Expiry Date:
2023-06-30

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

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