CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

AG Industries LLC

Main Site: 1031 Excecutive Parkway Drive,
St. Louis, Missouri, 63141, United States (FIN F002524)

Additional Site: Andador Vecinal 12001, Int L2-A, Tijuana-Tecate Baja California 22253 Mexico (FIN F002567)

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 medical filters as well as hospital and homecare products.

Additional site: WH, shipping & receiving, molding, assembly, and QMS

Certificate Number:
0092896

Initial Certification Date:
2019-07-22

Certification Effective Date:
2019-07-22

Certification Expiry Date:
2022-07-21

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Intertek

Calin Moldovean
President, Business Assurance

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