

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Advanced Medical Inc. D.B.A. Vygon USA

Main Site: 2750 Morris Rd., Lansdale PA 19446 United States (FIN F004543)

Additional Site: 87 Venture Drive, Dover, NH 03820 United States (FIN F004544)

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

ISO 13485:2016

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)

The management system is applicable to:

Main Site: The design, manufacture, repackaging, and distribution of medical devices and accessories for vascular access, local anesthesia, digestive and respiratory access, procedure kits. Medical device contract manufacturing services.

Additional Site: The design, manufacture, repackaging, and distribution of medical devices and accessories for vascular access, local anesthesia, digestive and respiratory access, procedure kits. Medical device contract manufacturing services.

Certificate Number:

0100331-02

Initial Certification Date:

2020-03-31

Certification Effective Date:

2020-06-30

Certification Expiry Date:

2023-03-31



Intertek

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