

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

WR Medical Electronics Co.

(FIN F003992)

Main Site: 1700 Gervais Avenue

Maplewood, Minnesota, 55109, 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)

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:

Design and Manufacture of paraffin therapy baths and refill paraffin and the design, manufacture and service of facial nerve monitors and facial nerve monitors and facial nerve stimulator/monitors, computer aided sensory evaluators, quantitative sweat measurement devices, and neurological testing management software.

Certificate Number:

0092541-01

Initial Certification Date:

2019-07-05

Certification Effective Date:

2022-07-04

Certification Expiry Date:

2025-07-04





President, Business Assurance

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



