

## **CERTIFICATE**OF 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 stimulator/monitors, quantitative sensory threshold evaluators, quantitative sweat measurement devices, iontophoresis controllers and electrodes, and neurological testing management software.

**Certificate Number:** 

0092541

**Revision Level: 03** 

**Initial Certification Date:** 

2019-07-05

**Certification Effective Date:** 

2025-07-04

**Certification Expiry Date:** 

2028-07-04



MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

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