



America

CERTIFICATE

No. QS6 048163 0006 Rev. 03

Certificate Holder: VARTA Microbattery GmbH
VARTA-Platz 1
73479 Ellwangen
GERMANY

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Rechargeable and Non-Rechargeable Batteries for Medical Applications and Hearing-Aids

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Health Canada. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F001366

Effective Date: 2022-06-22

Expiry Date: 2024-06-05

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Date of Issue: 2022-06-23

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services



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Regulatory Requirements: **Audit/Certification Criteria**
Canada
- Medical Device Regulations – Part 1- SOR 98/282

Facility(ies): VARTA Microbattery GmbH
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