



# CERTIFICATE

No. QS6 048163 0006 Rev. 00

Certificate Holder: **VARTA Microbattery GmbH**  
Daimlerstraße 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 <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **34-389-9485**

Effective Date: **2018-11-08**

Expiry Date: **2021-06-05**

Page 1 of 2

Date of Issue: 2018-11-16

( Arie Henkin )  
Manager, Certification Body MHS

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US-Letter / 07.17



America

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No. QS6 048163 0006 Rev. 00

**Regulatory Requirements:** Audit/Certification Criteria

**Canada**

- Medical Device Regulations SOR/98-282, Part 1

**Facility(ies):**

VARTA Microbattery GmbH

Daimlerstraße 1, 73479 Ellwangen, GERMANY

**Facility Scopes:**

Design and Development, Production and Distribution  
of Rechargeable and Non-Rechargeable Batteries for  
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Page 2 of 2

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