ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 099740 0002 Rev. 00

Certificate Holder: **Ava AG**
Gutstrasse 73
CH-8055 Zurich
SWITZERLAND

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution, and Servicing of Medical Bracelet and Software for Pregnancy-Related Feedback and for the Identification and Prediction of the Fertile Window**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, USA FDA, MHLW / PMDA. 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: **48-004-6979**

Effective Date: **2018-09-25**

Expiry Date: **2021-09-24**

Date of Issue: 2018-10-08

(Arie Henkin)

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: **Audit/Certification Criteria**

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

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):
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