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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 095360 0010 Rev. 00

Certificate Holder: **ivWatch, LLC**
1100 Exploration Way, Suite 209
Hampton VA 23666
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution, and Servicing of Electronic Non-Invasive Monitoring Devices in the Field of Intravenous (IV) Therapy**

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 http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

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

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(Arie Henkin)

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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): ivWatch, LLC
1100 Exploration Way, Suite 209, Hampton VA 23666, USA

Facility Scopes: Design and Development, Production, Distribution, and Servicing of Electronic Non-Invasive Monitoring Devices in the Field of Intravenous (IV) Therapy

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(Arie Henkin)

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