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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 095360 0016 Rev. 00**

**Manufacturer:** **ivWatch, LLC**  
700 Tech Center Parkway, Suite 300  
Newport News VA 23606  
USA

## **Product Category(ies): Infiltration and Extravasation Monitoring System**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 72156320

**Valid from:** 2020-03-25  
**Valid until:** 2024-05-26

**Date,** 2020-03-25

Christoph Dicks  
Head of Certification/Notified Body



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Product Service

# EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

**No. G2S 095360 0017 Rev. 00**

## Manufacturer

**ivWatch, LLC**

700 Tech Center Parkway, Suite 300  
Newport News VA 23606  
USA

## Product Category(ies):

**Sterile Securement Device for  
Infiltration and Extravasation Sensor**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** 72156737

**Valid from:** 2020-03-25

**Valid until:** 2024-05-26

**Date,** 2020-03-25

Christoph Dicks  
Head of Certification/Notified Body