ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 11 97418 005**

**Manufacturer:**

**AliveCor, Inc.**
444 Castro Street, Suite 600
Mountain View CA 94041
USA

**EC-Representative:**

**OBELIS S.A**
Avenue de Tervuren, 34, bte 44
1040 Brussels
BELGIUM

**Product Category(ies):**

**Ambulatory Electrocardiographs and Software and Algorithms used in Screening, Diagnosis and Management of Heart Rhythm Disorders**

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.:** 72133041

**Valid from:** 2018-01-15
**Valid until:** 2023-01-14


**Date,** 2018-01-08

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123







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TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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