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 15 05 39212 018**

**Manufacturer:**

**Osypka Medical GmbH**
Albert-Einstein-Strasse 3
12489 Berlin
GERMANY

**Product Category(ies):**

**Therapeutic and diagnostic cardiovascular medical products, class IIa/IIb: monitoring systems, pacing system analyzers, external pacemakers and related accessories**

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.:** 713061148

**Valid from:** 2015-06-21
**Valid until:** 2020-06-20

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**Date,** 2015-06-16

Hans-Heiner Junker

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





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**Facility(ies):**

Osypka Medical GmbH
Albert-Einstein-Strasse 3, 12489 Berlin, GERMANY

**Design Facility(ies):**

Osypka Medical GmbH
Albert-Einstein-Strasse 3, 12489 Berlin, GERMANY







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