

Translation

In any case, the german original shall prevail.

# CERTIFICATE

We hereby confirm that the company  
**Erkodent Erich Kopp GmbH**

Siemensstr. 3  
72285 Pfalzgrafenweiler

has implemented and maintains a

## Quality Management System

for the whole company

in accordance with

### **DIN EN ISO 9001 : 2008**

- additional requirements of DIN EN ISO 13485: 2012

Compliance with the requirements has been proved by means of an audit,  
documented in report Nr. 2014/013.

The certificate with the number **RCI 14002** shall remain valid until **2017-06-29**.

Langenhagen, 2014-06-30



Dipl.-Ing. Christian Pallowski



## **Annex 1**

### **to certificate RCI 14002 quality management system**

Additional the requirements for quality management system by

DIN EN ISO 9001: 2008

the requirements of

**DIN EN ISO 13485: 2012**

have also been taken into account. The audit results regarding the requirements of DIN EN ISO 13485: 2012 have been documented together with the results for the quality management system by DIN EN ISO 9001: 2008 with audit report 2014/013.

#### **Area of application:**

Development, production and distribution of dental-medical  
as well as orthopaedic/podologic

**non-sterile medical devices of class 1**

Langenhagen, 2014-06-30



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Dipl.-Ing. Christian Pallowski