

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 591452**
Issued To: **ZL Microdent Attachment GmbH & Co KG**
Harkortstr. 2
Breckerfeld
58339
Germany

In respect of:

Manufacture of non-sterile dental attachments and related accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2016-06-22**

Date: **2019-02-14**

Expiry Date: **2023-08-06**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

ZL Microdent Attachment GmbH & Co KG
Harkortstr. 2
Breckerfeld
58339
Germany

Holds Certificate Number:

MD 591451

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Manufacture and sales of non-sterile dental attachments and accessories. Contract-
Manufacture of sterile and non-sterile dental implants, abutments and accessories.

Previous certificate expired on 2018/08/05
Recertification audit ended 2018/05/30



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-17

Latest Revision Date: 2018-08-14

Effective Date: 2018-08-14

Expiry Date: 2021-08-06

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Certificate No: **MD 591451**

Location

ZL Microdent Attachment GmbH & Co KG
Harkortstr. 2
Breckerfeld
58339
Germany

Registered Activities

Manufacturing of products for dental and medical technique.
Herstellung von Produkten für die Dental- und Medizintechnik



Original Registration Date: 2016-06-17

Latest Revision Date: 2018-08-14

Effective Date: 2018-08-14

Expiry Date: 2021-08-06

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No.**CE 591452**

Issued To:

**ZL Microdent Attachment GmbH & Co KG
Harkortstr. 2
Breckerfeld
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In respect of:

Manufacture of non-sterile dental attachments and related accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2016-06-22**Date: **2018-09-10**Expiry Date: **2023-08-06**

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