

EC Certificate - Product Quality Assurance

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

No. CE 572913
Issued To: Gesellschaft für Funktionsdiagnostik
DIR-System mbH Co. KG
Bocholder Strasse 5
45355 Essen
Germany

In respect of:

Those aspects of Annex VI relating to metrology in the final inspection and testing of dental diagnostic devices.

Die Aspekte zur Messtechnik des Anhangs VI bei der Endkontrolle von Geräten zur dentalen Diagnostik.

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

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



Frank Lee, EMEA Compliance & Risk Director

First Issued: **29 June 2016**Date: **29 June 2016**Expiry Date: **20 April 2018**

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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.

EC Certificate - Product Quality Assurance Certificate History

Certificate No: **CE 572913**
 Date: **29 June 2016**
 Issued To: **Gesellschaft für Funktionsdiagnostik
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Date	Reference Number	Action
29 June 2016	8536380	First issue. Transfer from another Notified Body.

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