

EC Certificate - Product Quality Assurance

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

No. **CE 576175**
Issued To: **automation & software**
Günther Tausch GmbH
Lindenstr. 63
17033 Neubrandenburg
Germany

In respect of:

Final inspection and test of devices CORAscan for stress level evaluation based on the analysis of the heart rate variability.

Endkontrolle von Geräten CORAscan zur Stresslevelbewertung basierend auf der Analyse der Herzfrequenzvariabilität.

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: **22 June 2016**

Date: **22 June 2016**

Expiry Date: **03 October 2020**

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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 576175**
 Date: **22 June 2016**
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Date	Reference Number	Action
22 June 2016	8442269	First issue. Transfer from another Notified Body.

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