

EC Certificate - Product Quality Assurance

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

No.**CE 656804**

Issued To:

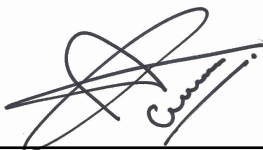
**tic Medizintechnik GmbH & Co. KG
Endelner Feld 9
46286 Dorsten
Germany**

In respect of:

Final inspection and test of electrostimulation devices and vacuum erection aids.**Endkontrolle und Prüfung von Elektrostimulationsgeräten und Vakuumerektionshilfen.**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2016-06-28**Date: **2019-02-13**Expiry Date: **2021-06-27**

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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.

EC Certificate - Product Quality Assurance Certificate History

Certificate No: **CE 656804**
 Date: **2019-02-13**
 Issued To: **tic Medizintechnik GmbH & Co. KG**
Endelner Feld 9
46286 Dorsten
Germany

Date	Reference Number	Action
28 June 2016	8536375	First issue. These devices were previously certified by another Notified Body.
Current	8708428	Traceable to NB 0086.

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