

EC Certificate - Production Quality Assurance

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

No. CE 66745
Issued To: Catheter Research, Inc.,
dba.Thomas Medical
6102 Victory Way
Indianapolis
Indiana
46278
USA

In respect of:

Those aspects of Annex V related to securing and maintaining sterility in the manufacture of sterile uterine manipulators/injectors, uterine injectors, hysterosalpingography and sonohysterography catheters, intra-uterine insemination catheters, endometrial samplers, cervical dilators, uterine sounds and embryo transfer catheters.

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 April 2003**

Date: **16 June 2016**

Expiry Date: **31 March 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.