



Production Quality Assurance

No. CE 66745

Issued to:

**Catheter Research, Inc.,
dba. Thomas Medical, Inc
5610 W 82nd Street
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, uterine injectors, hysterosalpingography and sonohysterography catheters, endometrial samplers, cervical dilators and uterine sounds.

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

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

Alastair Trivett, Managing Director, BSI Product Services – Global

First issued: 1 Apr 2003

Date: 27 Mar 2008

Expiration Date: 31 Mar 2013

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

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.

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