bsi.

By Royal Charter

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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