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 and uterine sounds.

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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2003-04-01** Date: **2018-03-21** Expiry Date: **2023-03-31**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 66745**
Date:	**2018-03-21**
Issued To:	**Catheter Research, Inc., dba.Thomas Medical 6102 Victory Way Indianapolis Indiana 46278 USA**

Subcontractor:	**Service(s) supplied**
Centurion Sterilization Services A Division of Centurion Medical Products Corporation 301 Catrell Drive Howell Michigan 48843 USA	**ETO Sterilization**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	**Gamma Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
01 April 2003		First Issue.
21 March 2007		Change to company address.
29 June 2007		Add to scope new devices, hysterosalpingography and sonohysterography catheters, endometrial samplers, cervical dilators and uterine sounds. Addition of Steris Isomedix to the list of subcontractors.
27 March 2008	7157441	Certificate Renewal.
30 April 2012	7830821	Addition of Emergo Europe as EU Representative.
11 March 2013	7947354	Certificate renewal. Updated name of subcontractor Centurion Sterilization Services, A Division of Centurion Medical Products Corporation (formerly Centurion Sterilization Services, A Division of Tri-State Hospital Supply). Addition of intra-uterine insemination catheters to scope.
08 April 2014	8138966	Update to company name from Catheter Research, Inc., dba. Thomas Medical, Inc to Catheter Research, Inc., dba. Thomas Medical.
27 February 2015	8281691	Addition of embryo transfer catheters and subcontractor Anderson Scientific, Inc., Morrisville, North Carolina, USA.
16 June 2016	8536095	Change of address to 6102 Victory Way, Indianapolis, IN 46278.

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Date	Reference Number	Action
Current	8901227	Certificate renewal. Change of EU Rep information. Removal of embryo transfer catheters from scope of certification. Removal of Andersen Scientific Inc. as significant sub-contractor for ETO sterilization.