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Certificate

Full Quality Assurance

No. CE 593447

Issued to:

Hensler Surgical Products LLC
2420 South 17th Street, Suite G
Wilmington
North Carolina
28401
USA

In respect of:

Design, development, and manufacture of sterile, single use autologous bone filtration system

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

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

Gary Fenton, Global Assurance Director

First Issued: **15 May 2013**

Date: **15 May 2013**

Expiration Date: **14 May 2018**

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.

...making excellence a habit.™

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL UK. A member of the BSI Group of Companies.

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List of Significant Subcontractors

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

Certificate No.	**CE 593447**
Date:	**15 May 2013**
Issued to:	**Hensler Surgical Products LLC** **North Carolina** **USA**

Subcontractor	Service(s) supplied
Medical Murray, Inc. 400 North Rand Rd. North Barrington Illinois USA 60010	Manufacture
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	ETO Sterilization
Northwest Clinical Research Group, Inc. 24125 85th Avenue SE Woodinville Washington USA	Quality Assurance Regulatory Compliance
Emergo Europe Molenstraat 15 2123 BH The Hague Netherlands	EU Representative

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Certificate

History of Quality Assurance Certificate

Certificate No: **CE 593447**

Date: **15 May 2013**

Issued to: **Hensler Surgical Products LLC**
North Carolina
USA

Date	Reference Number	Action
15 May 2013	7917046	First issue

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