

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 694788****Issued To:**

**Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA**

In respect of:

**The design, development, and manufacturing of occluders, plugs, delivery and exchange systems, catheters, sheaths, introducers, guidewires, sizing balloons, and related accessories for cardiovascular occlusion and vascular closure.
Those aspects of Annex II related to securing and maintaining sterility in the respect of sizing plates.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-09-03**

Date: **2020-10-15**

Expiry Date: **2023-02-23**

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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.

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List of Significant Subcontractors

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

Certificate No: **CE 694788**
 Date: **2020-10-15**
 Issued To: **Abbott Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Subcontractor:	Service(s) supplied
Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	EU Representative Labelling Packaging
Creganna Medical also doing business as Creganna Tactx Medical 5905 Trenton Lane North Plymouth MN 55442 USA	Manufacture
Creganna Medical also doing business as LSA 5015 Cheshire Parkway Plymouth Minnesota 55446 USA	Manufacture

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Subcontractor:

Service(s) supplied

Isomedix Operations Inc.
 380 90th Avenue NW
 Minneapolis
 Minnesota
 55433
 USA

ETO Sterilization

Lake Region Medical Ltd.
 Butlersland
 New Ross
 Co. Wexford
 Ireland

Manufacture

Midwest Sterilization Corporation
 1204 Lenco Avenue
 Jackson
 Missouri
 63755
 USA

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Subcontractor:	Service(s) supplied
St. Jude Medical Costa Rica Ltda. Edificio #44B Calle 0, Ave. 2 Zona Franca Coyoil El Coyoil, ALAJUELA Costa Rica	Manufacture
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	ETO Sterilization
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	ETO Sterilization

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Service(s) supplied

Synergy Health AST SRL
 B13.1 Street 4, Avenue 1
 El Coyol Free Zone
 20102 El Coyol
 Alajuela
 Costa Rica

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Certificate History

Certificate No: **CE 694788**
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Date	Reference Number	Action
03 September 2018	8955540	First Issue. Mirror certificate to CE 590631.
20 February 2019	8243107	Traceable to NB 0086.
20 March 2019	9738454	Addition of Sterigenics US, LLC, Salt Lake City, Utah USA as significant subcontractor for ETO Sterilization.
25 October 2019	3078721	Addition of subcontractor Midwest Sterilization Corporation, Jackson, Missouri USA for activity ETO Sterilization.
Current	3277497	Sterilization change from BIs to parametric release. Change affecting all ETO sterilized products covered by this certificate.

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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