

# EC Certificate - Full Quality Assurance System

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

**No.** CE 596074  
**Issued To:** Tyber Medical  
83 South Commerce Way  
Suite 310  
Bethlehem  
Pennsylvania  
18017  
USA

In respect of:

**Design and manufacture of sterile and non-sterile interbody implants, orthopaedic screws for osteosynthesis and fixation in small bones and joints, and associated instrumentation**

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: **2013-08-29**

Date: **2019-08-29**

Expiry Date: **2023-08-28**

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Page 1 of 1

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.

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

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

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

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**USA**

<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Axial Medical 65 Richard Rd. Ivyland Pennsylvania 18974 USA	<b>Manufacture</b>
BioPro, Inc. 2929 Lapeer Rd. Port Huron Michigan 48060 USA	<b>Packaging</b>
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	<b>Gamma Sterilization</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
MDSS GmbH Schiffgraben 41 Hannover 30175 Germany	<b>EU Representative</b>
Medical Device and Implants LLC 1824 Colonial Village Lane Lancaster PA 17601 USA	<b>Manufacture</b>
Oerlikon AM Medical Inc. 10 Constitution Blvd. South Shelton Connecticut 06484 USA	<b>Manufacture</b>

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**USA**

**Subcontractor:**

**Service(s) supplied**

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Orchid BioCoat  
23149 Commerce Drive  
Farmington Hills  
Michigan  
48335-2723  
USA

**Packaging**

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Surface Dynamics LLC  
231 Northland Blvd  
Cincinnati  
Ohio  
45246  
USA

**Manufacture**

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# EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
29 August 2013	7956909	First Issue
24 November 2017	8851131	Change of legal manufacturer address. Addition of subcontractor 'BioPro, Inc.' for Packaging Change of address for subcontractor 'Orchid BioCoat' to 23149 Commerce Drive, Farmington Hills, Michigan, 48335-2723, USA'.
29 August 2018	8923012	Addition of new critical subcontractors: 'Medical Device and Implants LLC, 1824 Colonial Village Lane, Lancaster, PA 17601, USA', 'Oerlikon AM Medical Inc., 10 Constitution Blvd. South, Shelton, Connecticut 06484, USA', 'Axial Medical, 65 Richard Road, Ivyland, Pennsylvania 18974, USA', and 'Surface Dynamics, LLC, 231 Northland Blvd., Cincinnati, Ohio 45246, USA'. Correct Subcontractor name from 'STERIS Isomedix Services' to 'Isomedix Operations, Inc.'
20 February 2019	7956915	Traceable to NB 0086.
Current	3050698	Addition of trauma screws for osteosynthesis procedures to scope.