By Royal Charter

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

List of Significant Subcontractors

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

Certificate No:	**CE 596074**
Date:	**2019-08-29**
Issued To:	**Tyber Medical** **83 South Commerce Way** **Suite 310** **Bethlehem** **Pennsylvania** **18017** **USA**

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

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

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Subcontractor:	**Service(s) supplied**
Orchid BioCoat 23149 Commerce Drive Farmington Hills Michigan 48335-2723 USA	**Packaging**
Surface Dynamics LLC 231 Northland Blvd Cincinnati Ohio 45246 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 596074**

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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.