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 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 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2013-08-29** Date: **2017-11-24** Expiry Date: **2018-08-28**

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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:	**2017-11-24**
Issued To:	**Tyber Medical** **83 South Commerce Way** **Suite 310** **Bethlehem** **Pennsylvania** **18017** **USA**

Subcontractor:	**Service(s) supplied**
BioPro, Inc. 2929 Lapeer Rd. Port Huron Michigan 48060 USA	**Packaging**
MDSS GmbH Schiffgraben 41 Hannover 30175 Germany	**EU Representative**
Orchid BioCoat 23149 Commerce Drive Farmington Hills Michigan 48335-2723 USA	**Packaging**

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Subcontractor:	**Service(s) supplied**
STERIS Isomedix Services 9 Apollo Drive Whippany New Jersey 07981 USA	**Gamma Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 596074**

Date: **2017-11-24**

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Date	Reference Number	Action
29 August 2013	7956909	First Issue
Current	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'.