

EC Certificate - Full Quality Assurance System

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

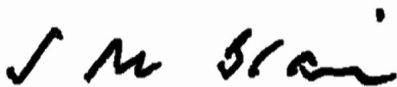
No. CE 596074
Issued To: Tyber Medical
83 South Commerce Way
Suite 310
Bethlehem
Pennsylvania
18017
USA

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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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.

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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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18017
USA

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
Issued To: Tyber Medical
 83 South Commerce Way
 Suite 310
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 18017
 USA

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'.

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Page 1 of 1

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