



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Biovision GmbH

Am Vogelherd 52
98693 Ilmenau
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Implants and products for treatments of wounds as listed according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	020807 MR2
Certificate unique ID	170647658
Effective date	2016-04-09
Expiry date	2019-12-13
Frankfurt am Main	2016-04-09

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to Certificate
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Device family	Device	Class
Implants	Bioresorbable Wedge MEGASHIM™	III
	Bioresorbable Screws Mega Fix® B Mega Fix® P Mega Fix® C Mega Fix® CP	III
	Bioresorbable Pins PolyPIN® 1.5 without x-ray marker PolyPIN® 2.0 without x-ray marker PolyPIN® 2.7 without x-ray marker	III
	Bioresorbable Pin for Membrane Fixation LeadFIX®	III
	Tricalcium phosphates BioResorb® BetaBASE® BioBASE®	III
	Products for Treatment of Wounds	Temporary Skin Replacement EpiGARD®