



# 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:

Bioresorbable 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 170769979

Effective date 2020-05-27

Expiry date 2024-05-26

Frankfurt am Main 2020-05-27

### 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**  
**Certificate registration No.: 020807 MR2**  
**Certificate unique ID: 170769979**  
**Effective date: 2020-05-28**



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Device family	Device	Class
<b>Implants</b>	Bioresorbable Screws	III
	Mega Fix® B	
	Mega Fix® P	
	Mega Fix® C	
	Mega Fix® CP	
	Bioresorbable Pins	III
	PolyPIN® 1.5 without x-ray marker	
	PolyPIN® 2.0 without x-ray marker	
	PolyPIN® 2.7 without x-ray marker	
	Bioresorbable Pin for Membrane Fixation	III
	LeadFIX®	
	SICbio pin™	
	Tricalcium phosphates	III
	BioResorb® Macro Pore	
	BioResorb® Classic	
<b>Products for Treatment of Wounds</b>	BetaBASE® MP	
	BioBASE® AP	
	BetaBASE®	
	BioBASE®	
	SICbio graft™	
	Temporary Skin Replacement EpiGARD®	IIb