

# Certificate

Full Quality Assurance System Approval  
Annex II excluding (4) of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

**Amedrix GmbH**

**Schelztorstr, 54-56, 73728 Esslingen, Germany**

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

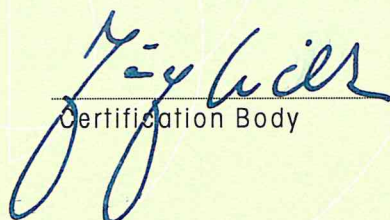
Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Report Number  
**628-14-56**

Registered under  
**Z/14/03367**

Valid until  
**June 30<sup>th</sup>, 2019**

Aachen, July 1<sup>st</sup>, 2014

  
Certification Body



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-926.94.08



Benannt durch/Designated by  
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ZLG-BS-240.10.12  
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Annex I of Certificate Z/14/03367

Date of revision: February 10<sup>th</sup>, 2017

Page 1 of 1



Zertifizierungsgesellschaft für  
Medizinprodukte in Europa mbH

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code
Nonactive implantable devices	Tissue Reconstructive Materials -- ChondroFiller gel -- ChondroFiller liquid	17-875

Special terms of validity:

None.