Certificate

EC Design Examination
Annex II.4 of the Directive on Medical Devices

ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that a design examination has been carried out on the device(s) listed in annex I to this certificate following the requirements of annex II.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 design of the device(s) listed in annex I to this certificate conforms with the requirements of annex II.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 examined product design or changes in the manufacturing process which might affect conformity to the essential requirements of the Directive 93/42/EEC or with the conditions prescribed for use of the product have to be notified to ECM and are subject to a separate approval.

Report Number	Registered under	Valid until
628-1591BD	Z/14/03369	June 30th, 2019

Aachen, July 1st, 2014

Certification Body

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZE-985.94.07

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-240.10.12

Annex I of Certificate Z/14/03369

ecm
Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code[1]
Nonactive implantable devices	Tissue Reconstructive Materials ChondroFiller®[1] -- HCFG-24 -- HCFG-26 -- HCFG-28 -- HCFG-44 -- HCFG-46 -- HCFG-48	17-875

Special terms of validity:

None.

[1] UMDNS Code ist optional