

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

628-30BDB9

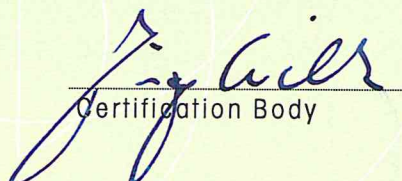
Registered under

Z/17/04012E

Valid until

February 9th, 2022

Aachen, February 10th, 2017


Certification Body



Annex I of Certificate Z/17/04012E

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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 liquid -- HCFL-10: 1,0 ml -- HCFL-15: 1,5 ml -- HCFL-23: 2,3 ml | 17-875 |

Special terms of validity:

None.

¹ UMDNS Code ist optional