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 undermentioned 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

AF Medical GmbH

Pfaffenhäule 60, 78224 Singen, 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.

The approved quality assurance system is subject to periodic surveillance as defined by annex II excluding (4), section 5.

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.

Audit Report Number	Registered under	Valid until
629-18-18	**Z/19/04614E**	**June 30th, 2021**

Valid as of: September 23rd, 2019

Certification Body

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de

ZLG-BS-240.10.12

Annex I of Certificate Z/19/04614E

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]
Non-active implantable products	Plates, Bone	13-050
Non-active implantable products	Wires, Bone	16-104
Non-active implantable products	Screws, Bone	16-101
Non-active implantable products	Nails, Bone	16-078

Special terms of validity:

None.

[1] UMDS Code is optional