Certificate

Production Quality Assurance System Approval
Annex V 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 V of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

Meditec Source GmbH & Co. KG
Sattlerstraße 19, 78532 Tuttlingen-Nendingen, Germany

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

The approved quality assurance system is subject to periodic surveillance as defined by Annex V, section 4.

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 V of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Report Number	Registered under	Valid until
508-19-73	**Z/19/04594E**	**July 23rd, 2024**

Valid as of: July 24th, 2019

Certification Body

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

Annex I to Certificate Z/19/04594E

Number of Pages: 1 of 1

This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code[1]
Reusable instruments	Calipers, Other	16-417
Reusable instruments	rulers	/
Reusable instruments	depth gauge	/
Reusable instruments	calipers	/
Reusable instruments	awl	/
Reusable instruments	Burs, Other	15-204
Reusable instruments	Burs, Orthopedic	17-995
Reusable instruments	Screwdrivers, Bone	13-517

Special terms of validity:

In case of class I products or sterile procedure packs acc. to article 12 (3) of the Directive 93/42/EEC the intervention of ecm is limited to aspects of manufacture concerned with securing and maintaining sterile conditions respectively the conformity with the metrological requirements.

[1] UMDNS Code is optional