

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 under mentioned 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

CeMed GmbH

Im Oberdorf 41, 72419 Neufra, 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

040-17-912

Registered under

Z/18/04206E

Valid until

March 27th, 2023

Aachen, March 28th, 2018


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 to Certificate Z/18/04206E

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 |
|--------------------------|---|--------------------------------|
| Single use devices | Casework, General-Purpose Procedure Packs (§10, Sec. 3) | 15-896 |
| Single use devices | Drapes, Surgical, Disposable | 15-646 |
| Single use devices | Scrub Dresses, Disposable | 13-522 |
| Single use devices | Cannulae, Other | 15-206 |

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