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 under mentioned 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

Zeolith-Bentonit-Versand.de

Eichendorffstraße 35, 09131 Chemnitz, 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
875-17-821	Z/17/04118E	September 14th, 2022

Aachen, September 15th, 2017

Certification Body

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

Annex I of Certificate Z/17/04118E

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
Single use devices	Spill Kits - Zeolith MED - Bentonit MED - Zeobent MED	17-488

Special terms of validity:

None.

UMDS Code is optional