

# 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

**TRIGOCare International GmbH**  
In den Wiesen 3; 51674 Wiehl; 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**

**539-18-111**

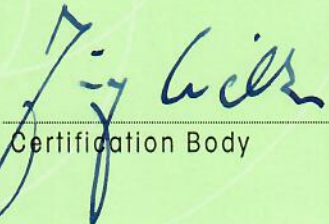
**Registered under**

**Z/18/04184E**

**Valid until**

**February 12<sup>th</sup>, 2023**

Aachen, February 13<sup>th</sup>, 2018

  
Certification Body



## Annex I of Certificate Z/18/04184E

Date of revision: August 24<sup>th</sup>, 2018

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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
single use devices	Dressings, Germicidal	11-324
single use devices	Bandages, Self-Adherent	10-288
single use devices	Dressings, Foam	11-323
single use devices	Dressings, Nonadherent	11-325
single use devices	Dressings, Fluff	11-751
single use devices	Dressings, Burn	11-322

Special terms of validity:

None.