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

WERO GmbH & Co. KG
Idsteiner Str. 94, 65232 Taunusstein, 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
031-18-315	Z/18/04303E	September 30th, 2023

Valid as of: September 29th, 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/18/04303E

Number of Pages: 1 of 1

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]
Single use device	Eye Pads	11-661
Single use device	Compresses, Gauze	10-966
Single use device	Compresses	10-965
Single use device	Bandages, Other	15-203
Single use device	Dressings, Universal	11-328
Single use device	Dressings, Burn	11-322
Single use devices	Bandages, Pressure	10-284
Reusable Instruments	Masks, Other	15-230
Single use devices	Medical Bags	12-500
Single use devices	Cold Packs	10-932
Single use devices	Dressings, Other	15-216

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