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

HGV-Verbandstoffe GmbH
Bahnhofstraße 2, 31698 Lindhorst, 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.

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
587-16-114	Z/17/03992E	January 12th, 2022

Aachen, January 13th, 2017

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/17/03992E

Date of revision: February 23rd, 2017
Number of Pages: 1 of 1

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[1]
single use devices	sterile sets: disposable instruments made of steel, (sterile procedure packs acc. article 12 MDD)	/
single use devices	surgical sets (sterile procedure packs acc. article 12 MDD)	/
single use devices	variable sets (sterile procedure packs acc. article 12 MDD)	/
single use devices	catheters, obstetric and suture-sets (sterile procedure packs acc. article 12 MDD)	/
single use devices	steril-sets (sterile procedure packs acc. article 12 MDD)	/
single use devices	sponges, neuro	13-702

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 metrolog

[1] UMDNS Code is optional