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

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 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

EG – Konformitätserklärung EC Declaration of Conformity	Konfo.Erkl.Nr.: 1159 Seite: 1 von 1 Änd.Index 5 Datum: 30.01.2020

Wir,	We,
WERO GmbH & Co. KG Idsteiner Str. 94 D-65232 Taunusstein (auch Aufbewahrungsort der Technischen Dokumentation) (also place of keeping technical documentation)	
als alleinig verantwortlicher Aussteller dieser Konformitätserklärung erklären hiermit, dass die folgenden Produkte den Bestimmungen der Richtlinie 93/42/EWG (vom 14. Juni 1993 zuletzt geändert durch die Richtlinie 2007/47/EG vom 5. September 2007) und dem Medizinproduktegesetz (MPG) als nationale Umsetzung der Richtlinie entsprechen und die grundlegenden Anforderungen in Anhang I der Richtlinie erfüllt werden. Ein Konformitätsbewertungsverfahren nach Anhang V + VII der Richtlinie wurde unter Einbeziehung der benannten Stelle ECM GmbH, Aachen, CE 0481 durchgeführt. Die Produkte sind in die **Klasse IIa** eingestuft (gemäß Regel 2).	as alone being responsible issuer of this Declaration of conformity are declare that the following products are conform to the specifications of the Medical Device Directive 93/42/EEC (of 14 June 1993 as last amended by Directive 2007/47/EC of 5 September 2007) and to the Medical products code as national implementation of these directives. They meet the fundamentally requirements of directives as *nominated in appendix* I. Conformity assessment acc. Appendix V + VII of directive was carried out by involving of the named ECM GmbH, Aachen, CE 0481. Products are registered in **Class IIa** (under rule 2).
Artikelbezeichnung	Article description
Dr. Marx Replantat-Beutel S, Gr. 1 Hand (REF 220553) **Dr. Marx Replantat-Beutel M**, Gr. 2 Arm (REF 220554) **Dr. Marx Replantat-Beutel L**, Gr. 3 Bein (REF 220555)	**Dr. Marx Amputated Parts Bag S,** size 1 hand (REF 220553) **Dr. Marx Amputated Parts Bag M,** size 2 arm (REF 220554) **Dr. Marx Amputated Parts Bag L,** size 3 leg (REF 220555)
Die Forderungen auf verbrauchergerechte Produktqualität und Produktsicherheit werden durch ein Qualitätssicherungssystem gemäß DIN EN ISO 13485 und DIN EN ISO 9001 sowie durch Einhaltung der in der Technischen Dokumentation aufgelisteten Normen und Regelwerke erfüllt.	Requirements of good manufacturing process and user safety are made sure by a Quality Management according to DIN EN ISO 13485 and DIN EN ISO 9001 as well as through the keeping of the norms and rules of the technical documentation.
Die Konformitätserklärung ist gültig bis zum **30. September 2023**.	This declaration is valid until **September 30, 2023**.

Taunusstein, den 30.01.2020

Wolfram Michallik
Geschäftsführer und
Sicherheitsbeauftragter Medizinprodukte

General Manager and
Safety Manager Medical Devices

Thorsten Hombach
Qualitätsmanagementbeauftragter

Quality Manager

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