

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 under mentioned 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

mediprim GmbH

Donnersbergweg 1; 67059 Ludwigshafen am Rhein, 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.

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

551-18-1010

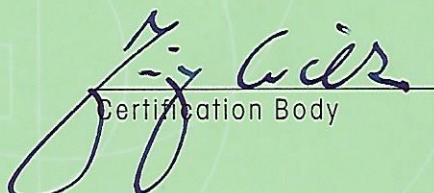
Registered under

Z/18/04381E

Valid until

November 28th, 2023

Valid as of: December 20st, 2018


Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-926.94.08



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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www.zlg.de
ZLG-BS-240.10.12

Annex I to Certificate Z/18/04381E

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use devices	Catheters, Urinary, Urethral, Drainage, Self-Retained Sterile Catheter Foley for Single Use	10-720
Single use devices	Urinary Collection Bags Sterile Urine Drainage Bag for Single Use	14-298
Single use devices	Catheters, Urinary, Ureteral Sterile Nelaton Catheter for Single Use	10-761
Single use devices	Gloves, Surgical Sterile Surgical Gloves for Single Use	11-883
Single use devices	Catheters, Urinary, External, Drainage Sterile Male External Catheter for Single Use	10-765
Single use devices	Syringes Sterile Syringe with Needle for Single Use Sterile Syringes for Single Use Sterile Safety Syringes for Single Use Sterile Auto Disable Syringes for Single Use	13-929

¹ UMDNS Code is optional

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use devices	Needles, Hypodermic Sterile Hypodermic Needles for Single Use	12-745
Single use devices	Intravenous Administration Sets, General-Purpose Sterile Infusion Sets for Single Use	16-649
Single use devices	Syringes, Other Sterile Insulin Syringes for Single Use	15-256
Single use devices	Intravenous Administration Sets, Scalp Vein Sterile Perfusion Set for Single Use Sterile Scalp Vein Set for Single Use Sterile Perfusion Set Butterfly for Single Use	17-825
Single use devices	Cannulae, Venous Sterile I.V. Catheter for Single Use Sterile Safety I.V. Catheter for Single Use	10-582

¹ UMDNS Code is optional

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use devices	Transfusion Kits Sterile Transfusion Sets for Single Use	14-126
Single use devices	Sampling Kits, Endometrial Sterile Endometrial Suction Curette for Single Use	11-531
Single use devices	Blades Sterile Surgical Blades for Single Use	15-558
Single use devices	Sampling Kits Sterile Gynaecological Kit for Single Use Sterile Urinary Swab for Single Use	15-596
Single use devices	Brushes, Cytology Sterile Cytological Brush for Single Use Sterile Cervical Brush for Single Use	15-018
Single use devices	Swabs, Antiseptic Sterile Cytological Swab for Single Use	13-913

¹ UMDNS Code is optional

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use devices	Swabs, Absorbent/Cotton	15-066
Single use devices	Knives, Scalpel Sterile Surgical Scalpels for Single Use Sterile Surgical Safety Scalpel for Single Use	12-252
Single use devices	Specula, Vaginal Sterile Vaginal Speculum for Single Use	13-666
Single use devices	Brushes Sterile Endometrial Brush for Single Use	10-500
Single use devices	Spatulas, Other Sterile Gynaecological Ayre Spatula for Single Use Sterile Gynaecological Szalay Spatula for Single Use Sterile Cervical Spoon for Single Use Sterile Transport Swab with Media for Single Use Sterile Transport Swab without Media for Single Use	15-249

¹ UMDNS Code is optional

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Single use devices	Bandages, Self-Adherent	10-288
Single use devices	Hydrogel Patches	/
Single use devices	Sheets, Drape, Disposable	15-705
Single use devices	Dressing Pads	11-326
Single use devices	Dressings, Nonadherent	11-325
Single use devices	Infusion Pumps, Micro	16-722
Single use devices	Needles, Blood Collection	12-736

¹ UMDNS Code is optional

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code ¹
Singel use devices	Tubes, Feeding Sterile Feeding Tube for Single Use	14-199

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