

Certificate

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2016.



Through an audit performed on behalf of

mediprim GmbH

Donnersbergweg 1; 67059 Ludwigshafen am Rhein, Germany

it could be demonstrated that a quality assurance system

according to

DIN EN ISO 13485:2016

“Medical devices – Quality management systems – Requirements for regulatory purposes”

for the

Manufacture and distribution of syringes, needles, gloves, products for infusion therapy, blood transfusion therapy, urology, gynaecology, gastroenterology, for wound treatment and surgical products.

has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number

551-18-1010

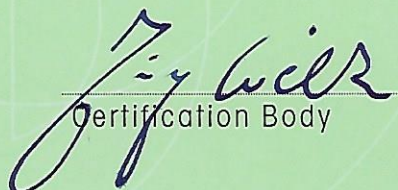
Registered under

Z/18/04380E

Valid until

December 20th, 2021

Valid as of: December 21st, 2018


Certification Body

Supplement to Annex I of Certificate Z/18/04380E

Pages 1 of 2



Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

The scope covers the following products:

Sterile Syringe with Needle for Single Use
Sterile Syringes for Single Use
Sterile Hypodermic Needles for Single Use
Sterile Surgical Gloves for Single Use
Sterile I.V. Catheter for Single Use
Sterile Safety I.V. Catheter for Single Use
Sterile Infusion Sets for Single Use
Sterile Transfusion Sets for Single Use
Sterile Endometrial Suction Curette for Single Use
Sterile Catheter Foley for Single Use
Sterile Nelaton Catheter for Single Use
Sterile Insulin Syringes for Single Use
Sterile Feeding Tube for Single Use
Sterile Gynaecological Kit for Single Use
Sterile Vaginal Speculum for Single Use
Sterile Gynaecological Ayre Spatula for Single Use
Sterile Gynaecological Szalay Spatula for Single Use
Sterile Cytological Brush for Single Use
Sterile Cervical Spoon for Single Use
Sterile Cytological Swab for Single Use
Sterile Urinary Swab for Single Use
Sterile Cervical Brush for Single Use
Sterile Transport Swab with Media for Single Use
Sterile Transport Swab without Media for Single Use
Sterile Safety Syringes for Single Use
Sterile Auto Disable Syringes for Single Use
Sterile Perfusion Set for Single Use
Sterile Scalp Vein Set for Single Use
Sterile Perfusion Set Butterfly for Single Use
Sterile Male External Catheter for Single Use

Supplement to Annex I of Certificate Z/18/04380E

Pages 2 of 2



Zertifizierungsgesellschaft für
Medizinprodukte in Europa mbH

Sterile Surgical Blades for Single Use

Sterile Surgical Scalpels for Single Use

Sterile Surgical Safety Scalpel for Single Use

Sterile Urine Drainage Bag for Single Use

Examination Gloves

Paris Bandage

Orthopaedic Padding

Alcohol Prep Pad

Plastic Tape

Fabric Tape

Herpes Patches

Hydrocolloid Patches

Hydorgel Patches

Theatre incise Drape

Dressing Pad

Paraffin Gauze Dressing

Infusions Pump

Blood Collection Cannula

Slides

Blood Collection Tube

Cover Glass, Microscope Slide

Tubes, Blood Collection

Sterile Urine Drainage Bag for Single Use