

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Rocket Medical also trading as Nusurgix Factories 2-4 Wear Industrial Estate,
Washington,
Tyne & Wear
United Kingdom

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 4008742/D

Original Approval: 29 August 2014

Current Certificate: 25 January 2017

Certificate Expiry: 28 August 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



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Rocket Medical also trading as Nusurgix Factories 2-4 Wear Industrial Estate, Washington, Tyne & Wear United Kingdom

<u>Class IIb Products</u> Sterile Tubes and Catheters - Extraction

Thoracic Catheters
Pigtail Drainage Catheters

Diathermy

Diathermy Loop Electrodes Bipolar Diathermy Forceps

IPC

Long Term Indwelling Catheters

Class IIa Products - Sterile

Tubes/Catheters – Extraction

Uterine Suction Catheters
Tubing set & Adapters
Feeding Tube Insertion Kit
Needle Introduced Drains
Wire Guided Drains
Plain Drainage Catheters
Dilators

IVF

Ureteric Stents
Oocyte Aspiration Needles
Aspiration Filter Sets

Needles - Aspiration;

Amniocentesis and CVS Needles Bone Biopsy Needles Chest Aspiration Sets





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Needles - Administration;

Injection Needles Access Needles Haemorrhoid Kits Insufflation Needles

Procedure Packs - Device Insertion and Care;

Drain Insertion Packs Pigtail Catheters Fixation Devices Guidewires

Procedure Packs - Sampling;

Foetal Blood Sampling Amniotic Hooks

Procedure Packs - Foetal Monitoring

Foetal Scalp Electrodes

Sterile Instruments

Blades

Punches

Haemorroid Ligators

Pumps

Filter sets

Non sterile Low Vacuum Aspiration Pumps

Portable Suction Unit

IPC

IPC Sets

IPC Dialators

Talc Poudrage

Talc Poudrage





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Class I Sterile Devices - Canister/Bottles

Chest Drainage Bottles
Tubing Sets
Urine Collection Pots
Fluid Collection Bags

Tubes/Catheters – Extraction

Suction Tubes Aspiration Kit

Tubes/Catheters – Administration

Sialography Catheters

IVF

Speculum

Uterine Cannula
Contrast Injection Catheters
Needle Guides & Accessories
Cervical Sampling Devices
Stylets
Gamete Transfer Catheters
Water Trap Set

Procedure Packs – Sampling

Amnilume
Endoscope
Lumbar Puncture Devices
Sterile Instruments
Single Use Instruments

IPC

Scissors

Drain Care Packs



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<u>Class I Measuring Devices</u> Canisters/Bottles

Chest Drainage Bottles Fluid Collection Bags

Procedure Packs – Sampling

Spinal Manometers

IPC

Evacuated Drainage Bottles

Schedule Issue: 02

Date of Schedule Issue: 25 January 2017

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