



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: 29 August 2016

Certificate Expiry: 28 August 2019

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited



EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 4008742/D SCHEDULE

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**Rocket Medical also trading as Nusurgix
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Class IIb Products

Sterile and Non-sterile Tubes and Catheters for;

Extraction;

Long Term Indwelling Catheters
Plain Drainage Catheters
Pigtail Drainage Catheters
Wire Guided Drains
Needle Introduced Drains
Uterine Suction Catheters
Cervical Suction Catheters
Thoracic Catheters

Diathermy Loop Electrodes

Class IIa Products

Administration;

Sialography Catheters
Perfusion Catheters
Enema Nozzles

Sterile Infertility, IVF and Associated Devices;

Oocyte Aspiration Needles
Gamete Transfer Catheters
Contrast Injection Catheters
Needle Guides
Aspiration Filter sets,
Ureteric Stents
Uterine Cannula

Class IIa Products

Sterile Needles for;

Aspiration;

Amniocentesis and CVS Needles
Bone Biopsy Needles
Chest Aspiration Sets





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Administration:

Injection Needles
Access Needles
Haemorrhoid Kits
Insufflation Needles

Sterile Procedure Packs and Devices for:

Device Insertion and Care:

Drain Insertion Packs
Drain Care Packs
Suture Insertion/Removal Packs

Sampling:

Foetal Blood Sampling
Lumbar Puncture Devices
Bone Marrow Biopsy
Amniotic Hooks

Foetal Monitoring Devices

Sterile Foetal Scalp Electrodes
Sterile Instruments
Single Use Instruments
Punches, Scissors and Blades
Haemorrhoid Ligator
Insufflation Filter
Smoke Venting Filter
Non-Sterile Low Vacuum Aspiration Pumps
Talc Poudrage





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Class I Sterile Devices

Sterile and non-sterile canisters, bottles and containers for storage;

Evacuated Drainage Bottles
Chest Drainage Bottles
Fluid Collection Bags
Urine Collection Pots
Enema Nozzles
Drain Care Packs
Sterile Single Use Instruments

Class I Measuring Devices

Spinal Manometer Sets

Schedule Issue: 01

Date of Schedule Issue: 29 August 2016

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