

The management system of

Rocket Medical Plc

Sedling Road, Washington,
Tyne and Wear, NE38 9BZ, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 17 June 2011 until 21 May 2015 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 21 May 2013

Issue 14. Certified since 28 October 1996

Certification is based on reports numbered GB/PC 06515

This is a multi-site certification.

Additional site details are listed on subsequent pages.

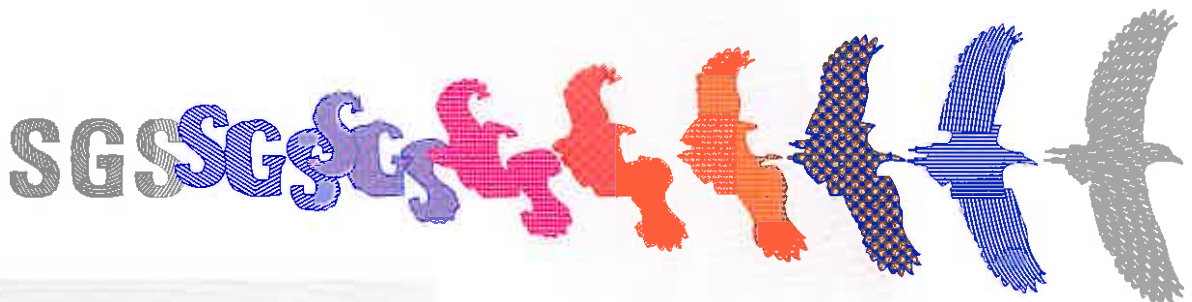
Authorised by

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Rocket Medical Plc

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 14

Detailed scope

Canister, Bottles and Containers for Drainage
Evacuated Drainage Bottles
Chest Drainage Bottles
Fluid Collection Bags
Urine Collection

Tubes and Catheters

a. Extraction:

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

b. Administration:

Sialography Catheters
Perfusion Catheters
Enema Nozzles

Infertility, IVF and Associated Devices

Oocyte Aspiration Needles
Gamete Transfer Catheters
Contrast Injection Catheters
Needle Guides
Aspiration Filter Sets

Needles

a. Aspiration

Amniocentesis and CVS Needles
Bone Biopsy Needles
Chest Aspiration Set

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on medical devices, Annex II (excluding Section 4)

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b. Administration

Injection Needles
Access Needles
Haemorrhoid Kits
Insufflation Needles

Procedure Packs and Devices

a. Device Insertion and Care

Drain Insertion Packs
Drain Care Packs
Suture Insertion/Removal Packs

b. Sampling

Fetal Blood Sampling
Lumbar Puncture Devices
Bone Marrow Biopsy

Fetal Monitoring Devices
Fetal Scalp Electrodes

Sterile Instruments
Single Use Instruments
Punches
Scissors and Blades
Diathermy Loop Electrodes

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certificate, an EC Design Examination Certificate according to Annex II
(Section 4) is required.**

Additional facilities

Imperial Way, Watford, Herts, WD2 4XX, UK