EC Certificate Full Quality Assurance System : Certificate GB20/965385

The management system of

Rocket Medical Plc.
also trading as Nusurgix

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

This certificate is valid from 18 May 2021 until 30 September 2022
And remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 29 August 2014.

Certification is based on reports numbered GB/PC 240728

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
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Rocket Medical Plc. also trading as Nusurgix

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope

Sterile and Non-Sterile thoracic catheters, pigtail drainage catheters, IPC long term indwelling catheters, uterine suction catheters, tubing set and adaptors, needle introduced drains, wire guided drains, plain drainage catheters and dilators
Sterile diathermy loop electrodes and bipolar diathermy forceps
KCH™ Fetal Bladder Drain and KCH™ Introducer Set
oocyte aspiration needles and aspiration filter sets used for in vitro fertilisation (IVF)
bone biopsy and chest aspiration sets
Sterile administration needles for injection, access, haemorrhoid kits and insufflation
Sterile procedure packs for device insertion and care containing drain insertion packs, pigtail catheters, fixation devices and guidewires
Sterile procedure packs for sampling containing foetal blood sampling devices and amniotic hooks
Sterile procedure packs for foetal monitoring containing foetal scalp electrodes
Haemorrhoid ligators
Sterile filter sets for pumps and portable suction units
Non-sterile low vacuum aspiration pumps
Sterile IPC Sets and dilators

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Corrigendum to Certificate GB20/965385

Rocket Medical Plc. also trading as Nusurgix

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Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Scope:

Sterile and Non-Sterile thoracic catheters, pigtail drainage catheters, IPC long term indwelling catheters, uterine suction catheters, tubing set and adaptors, needle introduced drains, wire guided drains, plain drainage catheters and dilators
Sterile diathermy loop electrodes and bipolar diathermy forceps
KCH™ Fetal Bladder Drain and KCH™ Introducer Set
oocyte aspiration needles and aspiration filter sets used for in vitro fertilisation (IVF)
bone biopsy and chest aspiration sets
Sterile administration needles for injection, access, haemorrhoid kits and insufflation
Sterile procedure packs for device insertion and care containing drain insertion packs, pigtail catheters, fixation devices and guidewires
Sterile procedure packs for sampling containing foetal blood sampling devices and amniotic hooks
Sterile procedure packs for foetal monitoring containing foetal scalp electrodes
Haemorrhoid ligators
Sterile filter sets for pumps and portable suction units
Non-sterile low vacuum aspiration pumps
Sterile IPC Sets and dilators

This corrigendum is only valid together with accompanying 93/42/EEC certificate issue 4

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Correction Date	Correction
Change approved by SGS on 30 June 2021	Addition of Injection Contrast Catheter which had been inadvertently missed off when transferring from LRQA to SGS (approved by Virginie Siloret)

Certificate GB20/965332

The management system of

Rocket Medical Plc.
also trading as Nusurgix

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture and distribution of sterile blood collection devices and kits, catheters and catheter insertion kits, CSF sampling devices, CTG electrodes, disposable surgical instruments, electrosurgical instruments, endoscopes, guide wires, irrigation/drainage devices and sets, needles, needle guides, surgical gloves, surgical sponges, syringes, Talc Poudrage Unit, wound dressings and haemorrhoid ligator and of nonsterile low vacuum aspiration pumps.

This certificate is valid from 17 February 2020 until 28 August 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 09 July 2022
Issue 1. Certified since 29 August 2014

Authorised by

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HC SGS 13485 2016 0118