EC Certificate Production Quality Assurance System: Certificate GB20/965386

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 V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions and the conformity of the devices with metrological requirements.

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 3. Certified since 29 August 2014.

Certification is based on reports numbered GB/PC/ 240728

Authorised by

Global Medical Devices Head of Notified Body

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Issue 3

Detailed scope

Metrological aspects only - Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements
- Cannisters, bottles and bags for collection of bodily fluids
- Procedure packs for sampling containing spinal manometers
- IPC evacuated drainage bottles

Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions
- Sterile and Non Sterile cannisters, tubing, bottles, bags and pots for drainage of bodily fluids
- Sterile cannula, catheters, needle guides, stylets, Gamete transfer catheters and water trap set used for in vitro fertilisation (IVF)
- Sterile procedure packs for device insertion and care including needle guide packs for in vitro fertilisation (IVF)
- Sterile procedure packs for sampling containing amnilume, endoscope and lumbar puncture devices
- Sterile IPC drain care packs

Where the above scope includes Class IIb or Class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in Addition to this certificate to place the device on the market.