

UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. UKCA 777329
Issued To: Rocket Medical Plc
Sedling Road
Washington
NE38 9BZ
United Kingdom

In respect of:

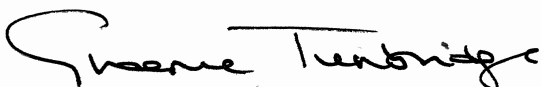
Those aspects of Annex V relating to securing and maintaining sterility of needle guides, obstetrics devices, drainage and fluid collection devices, gynaecological devices including IVF treatment and administration and aspiration filters

Those aspects of Annex V relating to metrology of drainage and fluid collection devices and cerebrospinal fluid pressure monitoring systems.

Those aspects of Annex V relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Regulation 14 of the UK MDR 2002

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2023-01-24**

Date: **2023-01-24**

Expiry Date: **2028-01-23**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

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Supplementary Information to UKCA 777329

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Number	Device Name	Intended purpose per IFU
Class Is		
MDS 7006	Needle guides	---
MDS 7006	Obstetrics devices	---
MDS 7006	Drainage and fluid collection devices	---
MDS 7006	Gynaecological Devices	---
MDS 7006	Administration and aspiration filters	---
Class Is, Im		
MDS 7006	Drainage and fluid collection devices	---
MDS 7006	Cerebrospinal Fluid Pressure monitoring systems	---

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Certificate History

Certificate No: **UKCA 777329**
Date: **2023-01-24**
Issued To: **Rocket Medical Plc**
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NE38 9BZ
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Date	Reference Number	Action
Current	3729811	Issued

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