Summary of Conformity according to Article 1

in accordance with Regulation 2023/607

Manufacturer's Name: Rocket Medical PLC

Business Address: Sedling Road, Washington, NE38 9BZ UK

EU Authorised Representative: Rocket Medical GmbH

AM Rosengarten 48, 15566 Schöneiche, Germany

Technical File Numbers:	TF_R001, TF_R006, TF_R007, TF_R008, TF_R012, TF_R013, TF_R015, TF_R017, TF_R018, TF_R019, TF_R022, TF_R025, TF_R026, TF_R029, TF_R030, TF_R031, TF_R038
Basic UDI-DI *(Part C of Annex VI)*:	See associated Technical File
Name of the Device(s)/Product:	Refer to Appendix A
SRN Number *(Article 31)*:	GB-MF-000025375
(EU) 2017/745 MDR Notified Body Name:	BSi Group the Netherlands B.V.
(EU) 2017/745 MDR Notified Body Address:	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands T: +31 (0)20 346 07 80
(EU) 2017/745 MDR Notified Body Identification Number:	2797
(EU) 2017/745 MDR Certificates issued by Notified Body in relation to this Declaration:	EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes; Certificate No.: 775566 Regulation 2017/745 EC Certificate of Quality Assurance, Certificate No.: 775549, European Medical Devices Regulation **Annex IX** (Chapter I & Section 4)
93/42/EEC MDD Notified Body Name:	SGS Belgium NV
93/42/EEC MDD Notified Body Address:	SGS House, Noorderlaan 87, 2030, Antwerp, Belgium T: +32 (0)3 545 48 48
93/42/EEC MDD Notified Body Identification Number:	1639
93/42/EEC MDD Certificates issued by Notified Body in relation to this Declaration:	EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes; Certificate No.: GB20/965332 Directive 93/42/EEC Certificate of Quality Assurance, Certificate No.: GB20/965385, Medical Devices **Annex II** (excluding Section 4). Directive 93/42/EEC Certificate of Quality Assurance, Certificate No.: GB20/965386, 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.

Product Code(s):	Refer to Appendix A
Risk Classification *(Annex VIII):*	Refer to Appendix A
Rule(s)	Refer to Appendix A
Conformity assessment procedure:	See associated Technical File
Common Specifications reference:	None applicable

Declaration:

This summary of conformity is issued under the sole responsibility of the manufacturer, Rocket Medical PLC. We hereby declare that the medical device(s) in scope of this declaration conform with and fulfil the applicable requirements of the Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This declaration will remain in force, for the devices listed in Appendix A, as per the stipulations of 2023/607, or until CE marking to the Medical Devices Regulation 2017/745, per device, is achieved, whichever is the sooner. The product scope of this declaration shall be updated via removal of devices being CE marked to the Medical Devices Regulation 2017/745.

All supporting documentation is retained at the premises of the manufacturer.

This declaration is issued at Washington, NE38 9BZ, UK on July 17th 2023 and has been signed on behalf of Robert Bernberg, Managing Director of Rocket Medical PLC



11 Mar 2024

Laura Hutchinson
Head of Quality and Regulatory Affairs at Rocket Medical Plc

This Declaration will be reviewed as per the above declaration.

Appendix A

TF_R001 Chest Drainage Bottles and Tubing Sets

Reference Code	Device Name	Classification	Rule
R54500	Chest Drainage Bottle (Single) with Droplet Control Shroud	Class Ism	I
R54509	Chest Drainage Bottle with Droplet Control Shroud	Class Ism	I
R54517	Single Chamber Chest Drainage Bottle with Droplet Control Shroud & Tubing Set	Class Ism	I
R54564	Rocket Ambulatory Chest Drain Bag	Class Ism	I
R60557	Rocket Chest Drain Bottle 1800ml, Single	Class Im	I
R54500-RFE	Rocket Chest Drain Filter and Coupling Gasket	Class IIa	

Reference Code	Device Name	Classification	Rule
R54502	Rocket Chest Drain Tubing Set	Class Is	I
R54533	Rocket "Y" Type Chest Drain Tubing set	Class Is	I
R54536	2 Way Drainage with Tubing Set	Class Is	I
R54537	Rocket 3 Way Drainage with Tubing Set	Class Is	I
R54539	Rocket Tubing Set Without Connector	Class Is	I
R54555	Y Type Drainage Set - 2 Way	Class Is	I
R54556	Y Type Drainage Set - 3 Way	Class Is	I
R60594	Rocket Y - Set with connectors	Class Is	I

TF_R006 Percutaneous Drainage

Reference Code		Device Name	Classification	Rule
Thoracentesis Range				
R51551	ZPACK015	Rocket Thoracentesis Catheter 6Fg	Class IIa	7
R51551-08-00	ZPACK032	Rocket Thoracentesis Catheter 8Fg	Class IIa	7
Multipurpose Drainage Range				
R58810-06-30		Rocket Multipurpose Drain 6Fg x 30cm	Class IIa	7
R58810-14-30		Rocket Multipurpose Drain 14Fg x 30cm	Class IIa	7
R58800-84-30	ZPACK026	Rocket Ascitex Multipurpose Drainage Set 8Fg x 30cm	Class IIa	7
R58810-84-25		Rocket Multipurpose Drain 8Fg x 25cm Uncoated	Class IIa	7
R58810-84-30		Rocket Multipurpose Drain 8Fg x 30cm Uncoated	Class IIa	7
R58830-84-30		Rocket Multipurpose Locking Drain 8Fg x 30cm Uncoated	Class IIa	7
R58820-84-30		Rocket Multipurpose Drain 8Fg x 30cm Coated	Class IIa	7

R58830-10-30		Rocket Multipurpose Locking Drain 10Fg x 30cm	Class IIa	7
R58851-84-30		Rocket Multipurpose Catheter 8Fg x 30cm Uncoated	Class IIa	7
Needle Drain Range				
R58800-06-BD	ZPACK033	Rocket Multipurpose Blue Needle Drain Catheter	Class IIa	7
R58800-06-BK	ZPACK034	Rocket BLUE Needle Drain	Class IIa	7
R58800-08-SD	ZPACK035	Rocket Safety Drain Catheter	Class IIa	7
Seldinger Range				
R54544-12-00	ZPACK016	Rocket 12Fg Seldinger Catheter	Class IIa	7
R54544-12-PK	ZPACK017	Rocket 12Fg Seldinger Catheter Procedure Tray	Class IIa	7
R54544-12-SG	ZPACK018	Rocket 12Fg Seldinger Catheter with Safety Guard	Class IIa	7
R54544-18-00	ZPACK019	Rocket 18Fg Seldinger Catheter	Class IIa	7
R54544-18-PK	ZPACK020	Rocket 18Fg Seldinger Catheter Procedure Tray	Class IIa	7
R54544-18-SG	ZPACK021	Rocket 18Fg Seldinger Catheter with Safety Guard	Class IIa	7
R54549-16-PK	ZPACK022	Rocket 16Fg Seldinger Catheter Procedure Tray	Class IIa	7
R54549-20-PK	ZPACK023	Rocket 20Fg Seldinger Catheter Procedure Tray	Class IIa	7
Accessories				
R54544-CONN		Stepped Connector Male Luer Lock	Class Is	1
R58915-00-ML		Rocket Wide Bore Adaptor	Class Is	1
R58915		IR Drainage Connection Set	Class Is	1

TF_R007 HSG and HyCoSy Catheters

Reference Code	Device Name	Classification	Rule
R57422	HSG and HyCoSy Catheter - 5Fg	Class Is	5
R57422-00-ST	HSG and HyCoSy Catheter with Stylet - 5Fg	Class Is	5
R57424	HSG and HyCoSy Catheter - 7Fg	Class Is	5
R57424-00-ST	HSG and HyCoSy Catheter with Stylet - 7Fg	Class Is	5
R57430-CONE	Hysterocone - 6Fg	Class Is	5
R57432	HyView® HSG and HyCoSy Catheter – 5Fg	Class Is	5
R57432-00-ST	HyView® HSG and HyCoSy Catheter with Stylet - 5Fg	Class Is	5
R57433	HyView® HSG and HyCoSy Catheter - 7Fg	Class Is	5
R57433-00-ST	HyView® HSG and HyCoSy Catheter with Stylet - 7Fg	Class Is	5
R57422-00-PK	HSG Procedure Pack – 5Fg	Class Is	5
R57422-ST-PK	HSG Procedure Pack - 5Fg with Stylet	Class Is	5
R57424-00-PK	HSG Procedure Pack – 7Fg	Class Is	5
R57424-ST-PK	HSG Procedure Pack - 7Fg with Stylet	Class Is	5

TF_R008 Pleural Vent

Reference Code	Device Name	Classification	Rule
R54565	Pleural Vent Assembly	Class IIa Sterile	7
Accessories			
R54565-AL	Rocket Aspiration Line	Class Is	I
R54565-CP	Rocket Occlusion Plug	Class Is	I

TF_R012 Fetal Blood Sampling (FBS)

Reference Code	Device Name	Classification	Rule
R57010	FBS Blade – Plug Fitting	Class IIa	6
R57011	FBS Blade – Screw Fitting	Class IIa	6
R57011-HLDR	FBS Blade Holder	Class IIa	6
R57018-00-SW	FBS Kit - 5 x 55µL Capillary Tubes	Class IIa	6
R57024-00-SW	FBS Kit - 5 x 85µL Capillary Tubes	Class IIa	6
R57026-00-SW	FBS Kit - 5 x 100µL Capillary Tubes	Class IIa	6
R57028-00-SW	FBS Kit for Handheld Lactate Analysers	Class IIa	6
R57021-10-SW	FBS Sampling Wand with 5 x 100µL Capillary Tubes	Class IIa	6
R57021-55-SW	FBS Sampling Wand with 5 x 55µL Capillary Tubes	Class IIa	6
R57021-85-SW	FBS Sampling Wand with 5 x 85µL Capillary Tubes	Class IIa	6
R57016-LUME-NS	Standard FBS Amniosope & Amnilume™	I Sterile	5, 13
R57016-PLUS-NS	Long FBS Amnioscope & Amnilume™	I Sterile	5, 13
R57021	Capillary Tube Holder	I Sterile	5

TF_R013 IPC Insertion and Accessories

Reference Code	Device Name	Classification	Rule
R54400-16-MT	IPC Insertion Set with Metal Tunneler	Class IIb	8
R54400-16-MI	Rocket Post Vat Insertion Set	Class IIb	8
R54400-MINI	IPC Mini Insertion Kit	Class IIb	8
Accessories			
R54410-00-CP	Rocket IPC Replacement Valve Cap	Class Is	I
R54410-00-DL	Rocket IPC Drainage Line	Class Is	I
R54410-00-LX	Rocket IPC Extended Drainage Line	Class Is	I
R54410-00-VV	Rocket IPC Replacement Valve	Class Is	I
R54410-00-DL	Rocket IPC Drainage Line with Wide Bore Connector	Class Is	I

Reference Code	Device Name	Classification	Rule
R54410-16-11	Rocket IPC Split Sheath Dilator 16G x 11cm	Class IIa	6
R54410-16-17	Rocket IPC Split Sheath Dilator 16G x 17cm	Class IIa	6
R54400-00-RK	IPC Removal Kit	Class IIa	6

TF_R015 IPC Bottles, Bag and Dressing Pack

Reference Code	Device Name	Classification	Rule
R54400	IPC Dressing Pack and 500ml Bottle	Class IIa	11
R54410	Rocket IPC Pre-evacuated 500ml Bottle	Class IIa	11
R54400-DP	IPC Discharge Pack	Class IIa	11
R54411	Dressing Pack and 1000ml Bottle	Class IIa	11
R54411-00-00	Pre-evacuated 1000ml Bottle	Class IIa	11
R54401	2000ml Drainage Bag	Class Is	1
R54400-00-00	Rocket IPC dressing Pack	Class 1s	4

TF_R017 Aspiration Needles and Needle Guides

Reference Code	Device Name	Classification	Rule
R57601-SX-90	Rocket 16G SX Needle 33cm x 90cm Oxford Set	Class IIa	6
R57602-00-SX	Rocket 17G SX Needle 33cm x 70cm Tube Set	Class IIa	6
R57602-SX-90	Rocket 17G SX Needle 33cm x 90cm Oxford Set	Class IIa	6
R57603-SX-70	Rocket 17G SX Needle 35cm x 70cm Oxford Set	Class IIa	6
R57603-SX-90	Rocket 17G SX Needle 35cm x 90cm Oxford Set	Class IIa	6
R57610	Rocket Double Lumen Needle 16G x 32cm x 70cm Oxford Set	Class IIa	6
R57611	Rocket Double Lumen Needle 16G x 35cm x 70cm Oxford Set	Class IIa	6

Reference Code	Device Name	Classification	Rule
R57525-00-AK	Rocket Needle Guide For Aloka Probe UST984-5	Class Is	5
R57525-00-AL	Rocket Needle Guide For Aloka Probe UST9118 & UST9124	Class Is	5
R57525-00-EC	Rocket Needle Guide Siemens EC9-4 & EV9-4 Transducers	Class Is	5
R57525-00-ED	Rocket Needle Guide, Siemens EC7, EC10C5, EC-4 SONOLINE G20	Class Is	5
R57525-00-ES	Rocket Needle Guide For Esaote EC1123 ultrasound transducers	Class Is	5
R57525-00-EV	Rocket Needle Guide Siemens Endo V for Sonoline series probes	Class Is	5
R57525-00-GE	Rocket Needle Guide GE Healthcare for E72, E721, E8C, E8C-RS, IC5-9H, IC5-9, MTZ, MZ transducers	Class Is	5
R57525-00-GS	Rocket Needle Guide GE Voluson-S RIC5-9W-RS series probes	Class Is	5
R57525-00-H	Rocket Needle Guide HITACHI for EZU-PA5V compatible probes	Class Is	5
R57525-00-ME	Rocket Needle Guide for ALPINION E3-10, BK8819, Aloka UST-679, Philips BP10-5ec, C9-4ec, Medison NER4/NEV4-9ES	Class Is	5
R57525-00-PI	Rocket Needle Guide Philips CV8-4 probes	Class Is	5
R57525-00-T	Rocket Needle Guide Toshiba PVM-651 probes	Class Is	5

R57525-00-T3	Rocket Needle Guide Toshiba PVM 740RT, PVT 770RT	Class Is	5

TF_R018 IUI Catheters

Reference Code	Device Name	Classification	Rule
R57622	Embryon EDL IUI Catheter 18cm	Class Is	5
R57625	Embryon DUO IUI Catheter 18cm	Class Is	5
R57625-00-23	Embryon DUO IUI Catheter 23cm	Class Is	5

TF_R019 Embryo Transfer

Reference Code	Device Name	Classification	Rule
R57545	Embryon ET Catheter 18cm (Peel Pouch)	Class Is	5
R57570	Embryon ET Catheter Set 18cm (Tray Pack)	Class Is	5
R57630-00-18	Embryon Genesis ET Catheter 18cm	Class Is	5
R57630-00-23	Embryon Genesis ET Catheter 23cm	Class Is	5
R57630-EC-18	Embryon EchoCath ET Catheter 18cm	Class Is	5
R57630-EC-23	Embryon EchoCath ET Catheter 23cm	Class Is	5
R57635-00-18	Embryon Bulb Tip ET Catheter 18cm	Class Is	5
R57635-00-23	Embryon Bulb Tip ET Catheter 23cm	Class Is	5
R57635-EC-18	Embryon Bulb Tip Echogenic ET Catheter 18cm	Class Is	5
R57635-EC-23	Embryon Bulb Tip Echogenic ET Catheter 23cm	Class Is	5

Reference Code	Device Name	Classification	Rule
R57631-00-18	Embryon Genesis Trial Transfer Catheter 18cm (Trial run use – not for Embryo Transfer)	Class Is	5
R57631-00-23	Embryon Genesis Trial Transfer Catheter 23cm (Trial run use – not for Embryo Transfer)	Class Is	5
R57631-EC-18	Embryon Echocath Trial Transfer Catheter 18cm (Trial run use – not for Embryo Transfer)	Class Is	5
R57631-EC-23	Embryon Echocath Trial Transfer Catheter 23cm (Trial run use – not for Embryo Transfer)	Class Is	5
R57636-00-18	Embryon Bulb Tip Trial Transfer Catheter 18cm (Trial run use – not for Embryo Transfer)	Class Is	5
R57636-00-23	Embryon Bulb Tip Trial Transfer Catheter 23cm (Trial run use – not for Embryo Transfer)	Class Is	5

TF_R022 Pumps

Reference Code	Device Name	Classification	Rule
R29700	Oocyte Aspiration Pump (110-240V)	Class IIa	12
R29654	CRAFT™ Suction Pump (110V)	Class IIa	12
R29655	CRAFT™ Suction Pump (240V)	Class IIa	12
R29660	CRAFT™ DUO VAC™ Suction Pump (240V)	Class IIa	12

R29661	CRAFT™ DUO VAC™ Suction Pump (110V)	Class IIa	12
R54569	Rocket Portable Suction Unit	Class IIa	12
R54571	Rocket Suction Unit Filter	Class Is	1
R57679	Rocket Filter Set	Class Is	1
R57685	Water Trap Set for CRAFT™ Suction Pumps	Class Is	1
R57686	Filter Set for Oocyte Aspiration Pump	Class Is	1
R57687	Filter Set for Cook K-MAR-5200 Pump	Class Is	1

TF_R025 Haemorrhoidal Devices

Reference Code	Device Name	Classification	Rule
R56210	Haemorrhoidal Kit Straight	Class IIa	6
R56211	Haemorrhoidal Kit Angled	Class IIa	6

TF_R026 Pudendal Block

Reference Code	Device Name	Classification	Rule
R57040	Pudendal Block Needle – 6% Luer	Class IIa	6

TF_R029 CSF Pressure Measurement

Reference Code	Device Name	Classification	Rule
R55990	Rocket Spinal Manometer Set	Class Ism	1
R55990-ISO-6	Rocket Spinal Manometer Set	Class Ism	1

TF_R030 Fetal Scalp Electrode (FSE)

Reference Code	Device Name	Classification	Rule
R57008-00-CN	Rocket® Copeland® Fetal Scalp Electrode	Class IIa	7
R57008-00-FM	Rocket® Copeland® Fetal Scalp Electrode	Class IIa	7

TF_R031 Diathermy

Reference Code	Device Name	Classification	Rule
R57800	Ultra-Fine™ LLETZ Loop - 14mm	Class IIb	6
R57801	Ultra-Fine™ LLETZ Loop - 18mm	Class IIb	6
R57802	Ultra-Fine™ LLETZ Loop - 22mm	Class IIb	6
R57804	Ultra-Fine™ LLETZ Ball Electrode - 5mm	Class IIb	6
R57807	Ultra-Fine™ LLETZ Ball Electrode - 3mm	Class IIb	6

TF_R038 Thoracic Catheters

Reference Code	Device Name	Classification	Rule
R54549-26-PK	Rocket 26Fg Chest Catheter - Blunt Dissection Chest Drainage Insertion Pack	Class IIa	7
R54549-28-PK	Rocket 28Fg Chest Catheter - Blunt Dissection Chest Drainage Insertion Pack	Class IIa	7
R54549-32-PK	Chest Catheter - Blunt Dissection Chest Drainage Insertion Pack	Class IIa	7
R54691	Rocket Thoracic Catheter 14Fg Straight with Pull Through	Class IIa	7
R54694	Rocket Thoracic Catheter 18Fg Straight with Pull Through	Class IIa	7
R54700	Rocket Thoracic Catheter 24Fg Straight with Pull Through	Class IIa	7
R54701	Rocket 24Fg Chest Catheter - Straight Ended	Class IIa	7
R54704	Rocket Thoracic Catheter 28Fg Straight with Pull Through	Class IIa	7
R54706	Rocket Thoracic Catheter 32Fg Straight with Pull Through	Class IIa	7
R54708	Rocket Thoracic Catheter 36Fg Straight with Pull Through	Class IIa	7
R54747	Rocket Thoracic Catheter 14Fg Angled with Pull Through	Class IIa	7
R54750	Rocket Thoracic Catheter 18Fg Angled with Pull Through	Class IIa	7
R54756	Rocket Thoracic Catheter 24Fg Angled with Pull Through	Class IIa	7
R54760	Rocket Thoracic Catheter 28Fg Angled with Pull Through	Class IIa	7
R54762	Rocket Thoracic Catheter 32Fg Angled with Pull Through	Class IIa	7
R54764	Rocket Thoracic Catheter 36Fg Angled with Pull Through	Class IIa	7
R54790	Rocket Thoracic Catheter 28Fg Straight - Bulk Packed	Class IIa	7
R54799	Rocket Thoracic Catheter 20Fg Straight with Flared End	Class IIa	7
R54800	Rocket Thoracic Catheter 24Fg Straight with Flared End	Class IIa	7
R54804	Rocket Thoracic Catheter 28Fg Straight with Flared End	Class IIa	7
R54806	Rocket Thoracic Catheter 32Fg Straight with Flared End	Class IIa	7
R54850	Rocket Thoracic Catheter 24Fg Angled with Flared End	Class IIa	7
R54854	Rocket Thoracic Catheter 28Fg Angled with Flared End	Class IIa	7
R54856	Rocket Thoracic Catheter 32Fg Angled with Flared End	Class IIa	7

R60503	Rocket Thoracic Catheter 28Fg - Angled Bulk Packed	Class IIa	7
R60505	Rocket Thoracic Catheter 32Fg - Angled Bulk Packed Non-Sterile	Class IIa	7
R60559	Rocket Thoracic Catheter 28Fg Straight with Pull Through	Class IIa	7
R60560	Rocket Thoracic Catheter 32Fg Straight with Pull Through Non-Sterile	Class IIa	7

Appendix B

Article Regulation EU 2023/607	**Text from Regulation**	**Summary of Rocket Medical Compliance**
1(a)(a)	Before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device	NB agreement and date of signature: Q611204, 16 May 2022 MDD certificate referenced and expiry date: GB20/965385, 30 September 2022
1(b)(3)(a)	If all conditions are met, place on the market until: 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;	Products that fall under this category are: TF_R013 IPC Insertion & Accessories See sections 1(b)(3)(c)(a)-(e) for confirmation conditions are met.
1(b)(3)(b)	If all conditions are met, place on the market until: 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I	Products that fall under this category are: TF_R001 Chest Drainage Bottles & Tubing Sets TF_R006 Percutaneous Drainage TF_R007 HSG & HyCoSy Catheters TF_R008 Pleural Vent

Article Regulation EU 2023/607	Text from Regulation	Summary of Rocket Medical Compliance
	devices placed on the market in sterile condition or having a measuring function.	TF_R012 Fetal Blood Sampling (FBS) TF_R015 IPC Bottles, Bag & Dressing Pack TF_R017 Aspiration Needles & Needle Guides TF_R018 IUI Catheters TF_R019 Embryo Transfer TF_R022 Pumps TF_R025 Haemorrhoidal Devices TF_R026 Pudendal Block TF_R029 CSF Pressure Measurement TF_R030 Fetal Scalp Electrodes (FSE) TF_R031 Diathermy TF_R038 Thoracic Catheters See sections 1(b)(3)(c)(a)-(e) for confirmation conditions are met.
1(b)(3)(c)(a)	Those devices continue to comply with Directive 93/42/EEC	MDD Technical files: TF_N001 Bottles and Tubing Sets TF_N006 Percutaneous Drainage TF_N007 HSG & HyCoSy TF_N008 Pleural Vent TF_N012 Fetal Blood Sampling (FBS) TF_N013 IPC Insertion & Accessories TF_N015 IPC Bottles, Bag & Dressing Pack TF_N017 Aspiration Needles & Needle Guides TF_R018 IVF (IUI Catheters) TF_R019 IVF (Embryo Transfer) TF_N022 Pumps, TF_N026 Pudendal Block TF_N025 Haemorrhoidal Devices

Article Regulation EU 2023/607	Text from Regulation	Summary of Rocket Medical Compliance
		TF_N026 Pudendal Block TF_N029 CSF Pressure Measurement TF_N030 Fetal Scalp Electrodes (FSE) TF_N031 Diathermy TF_N035 Rectal Examination TF_N038 Thoracic Catheters are in place and until certificate expiry, were sampled as required by: SGS United Kingdom Ltd, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK Continued maintenance is achieved to EU MDR 2017/745 Article 120 requirements relating to post market surveillance, market surveillance, vigilance, and economic operator and device registrations Rocket Medical Plc SRN: GB-MF-000025375 Rocket Medical Plc Authorised Representative SRN: DE-AR-000011752 Associated PSUR's: TF_R001_22_02 Chest Drainage Bottles & Tubing Sets PSUR TF_R006_22_02 Percutaneous Drainage PSUR TF_R007_22_02 HSG PSUR TF_R008 _22_02 Pleural Vent PSUR TF_R012_22_02 Fetal Blood Sampling (FBS) PSUR TF_R013_22_02 IPC Catheter & Accessories PSUR

Article Regulation EU 2023/607	Text from Regulation	Summary of Rocket Medical Compliance
		TF_R015_22_02 IPC Bottles, Bag & Dressing Pack PSUR TF_R017_22_02 Aspiration Needles & Needle Guides PSUR TF_R018_22_02 IUI Catheters PSUR TF_R019_22_02 Embryo Transfer Catheters PSUR TF_R022_22_02 Pumps PSUR TF_R025_22_02 HD PSUR TF_R026_22_02 Pudendal Block PSUR TF_R029_22_02 CSF PSUR TF_R030_22_02 Fetal Scalp Electrodes (FSE) PSUR TF_R031_22_02 Diathermy PSUR TF_R038_22_02 Thoracic Catheters PSUR Furthermore, the ability of the Rocket Medical QMS to achieve these requirements was sampled in BSi audits: 3729577, 3729809, 3729840 held between 30-August – 02 September 2022 and subsequent audit 3774921, 3775850, 3775852, 3775853, 3775854 held 15 November 2022. This audit has been successfully closed Rocket Medical therefore declare continued compliance to Directive 93/42/EEC, given the activity it is performing and the historic technical files in place.
1(b)(3)(c)(b)	there are no significant changes in the design and intended purpose;	No significant changes have occurred: See Rocket Change Control System, QPulse, Software Version 6.8.4.4 for change log. There are no significant changes to design or intended purposes of the devices covered by this summary.

Article Regulation EU 2023/607	Text from Regulation	Summary of Rocket Medical Compliance
1(b)(3)(c)(c)	the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;	EU MDR 2017/745 Article 120 requirements relating to post market surveillance, market surveillance, vigilance, and economic operator and device registrations are followed for all the listed TF's. No unacceptable risks have been identified from last NB assessment to current time: Associated PSUR's: TF_R001_22_02 Chest Drainage Bottles & Tubing Sets PSUR TF_R006_22_02 Percutaneous Drainage PSUR TF_R007_22_02 HSG PSUR TF_R008 _22_02 Pleural Vent PSUR TF_R012_22_02 Fetal Blood Sampling (FBS) PSUR TF_R013_22_02 IPC Catheter & Accessories PSUR TF_R015_22_02 IPC Bottles, Bag & Dressing Pack PSUR TF_R017_22_02 Aspiration Needles & Needle Guides PSUR TF_R018_22_02 IUI Catheters PSUR TF_R019_22_02 Embryo Transfer Catheters PSUR TF_R022_22_02 Pumps PSUR TF_R025_22_02 HD PSUR TF_R026_22_02 Pudendal Block PSUR TF_R029_22_02 CSF PSUR TF_R030_22_02 Fetal Scalp Electrodes (FSE) PSUR TF_R031_22_02 Diathermy PSUR TF_R038_22_02 Thoracic Catheters PSUR

Article Regulation EU 2023/607	Text from Regulation	Summary of Rocket Medical Compliance
1(b)(3)(c)(d)	no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);	Quality management in accordance to EU MDR Article 10(9) is already in place and has been verified by BSi: BSi Audit Reports: 3729577, 3729809, 3729840 held between 30-August – 02 September 2022 and subsequent audit 3774921, 3775850, 3775852, 3775853, 3775854 held 15 November 2022. This audit has been successfully closed BSi Certificate number: MDR 775549
1(b)(3)(c)(e)	no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.	Formal application is complete. Written agreement signed: Q611204, 16 May 2022
1(b)(3)(d)	By way of derogation from paragraph 3 of this Article, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in paragraphs 3a and 3b of this Article in place of the corresponding requirements	EU MDR 2017/745 Article 120 requirements relating to post market surveillance, market surveillance, vigilance, and economic operator and device registrations are followed for all the listed TF's. No unacceptable risks have been identified from last NB assessment to current time. Quality management in accordance to EU MDR Article 10(9) is already in place and has been audited by BSi, thus demonstrating Rocket Medicals QMS is appropriate for post market surveillance, market

Article Regulation EU 2023/607	Text from Regulation	Summary of Rocket Medical Compliance
	in Directives 90/385/EEC and 93/42/EEC	surveillance, vigilance, and economic operator and device registrations. BSi Audit Reports: 3729577, 3729809, 3729840 held between 30-August – 02 September 2022 and subsequent audit 3774921, 3775850, 3775852, 3775853, 3775854 held 15 November 2022. This audit has been successfully closed Rocket Medical Plc SRN: GB-MF-000025375 Rocket Medical Plc Authorised Representative SRN: DE-AR-000011752