

# Manufacturer's Declaration

In relation to Regulation (EU) 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and/or<sup>1</sup>
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Quest Medical, Inc.
Manufacturer address and contact details	1 Allentown Parkway, Allen, TX 75002 972 390-9800
Single Registration Number (SRN) (if available)	US-MF-000008538

Authorised Representative name (if applicable)	Emergo Europe
Authorised Representative address and contact details	Westervoortsedijk 60, 6827 AT Arnhem, Netherlands
Single Registration Number (SRN) (if available)	NL-AR-000000116

Notified body name (if applicable)	TUV SÜD
Notified body number (if applicable)	0123 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 024751 0027 Rev. 00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2023-08-17  □ See attached schedule
End date of extended validity/transition period	⊠ See attached schedule

<sup>&</sup>lt;sup>1</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.



We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*<sup>2</sup>
- the listed device(s) in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

# > Directive Certificate(s) as listed above or in the attached schedule

		re Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were in 26 May 2021 and have not been withdrawn afterwards.
Cho	oose	e applicable statements:
	Exp	pired before 20 March 2023:
		Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)
		oose one of the following statements only if a derogation per Article 59(1) or a requirement Article 97(1) has been granted by a Competent Authority:
		Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
		We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024

<sup>&</sup>lt;sup>2</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body



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Choose one applicable statement:

- ☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or their substitute(s) and signed written agreement(s) are in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024. TUV SUD MDR/IVDR Framework Agreement was executed 13 July, 2023 (ref no. 24751).
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

#### > Upclassified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

#### Quality Management System (QMS)

Choose one applicable statement:

- ☑ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

#### > Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.



# Signed for and on behalf of the manufacturer:

Quest Medical, Inc.

1 Allentown Parkway, Allen TX 75002, 28 August, 2023

Signature

Dan Hodges
Printed Name

Lity Assurance + Regulatory Affairs

Email: jlhodges@questmedical.com

Phone: 972 390-9800



### **Schedule of Devices**

The above Manufacturer's Declaration is valid for the following device families:

Identification of the device(s) <sup>3</sup> (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Cardiovascular Surgical Devices	G1 024751 0027 Rev. 00	2023-08-17	TUV SÜD; 0123	TUV SÜD; 0123	2028-12-31	N/A
MPS Myocardial Protection System	G1 024751 0027 Rev. 00	2023-08-17	TUV SÜD; 0123	TUV SÜD; 0123	2028-12-31	N/A
Fluid Delivery Devices	G1 024751 0027 Rev. 00	2023-08-17	TUV SÜD; 0123	TUV SÜD; 0123	2028-12-31	N/A
Cardioplegia Catheters and Perfusion Sets	G1 024751 0027 Rev. 00	2023-08-17	TUV SÜD; 0123	TUV SÜD; 0123	2028-12-31	N/A
Manual Ophthalmic Surgical Devices	G1 024751 0027 Rev. 00	2023-08-17	TUV SÜD; 0123	TUV SÜD; 0123	2028-12-31	N/A
Intravenous Administration Sets	G1 024751 0027 Rev. 00	2023-08-17	TUV SÜD; 0123	TUV SÜD; 0123	2028-12-31	N/A

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<sup>&</sup>lt;sup>3</sup> for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)



# Device(s) covered under this certification

The above Manufacturer's Declaration is valid for the following devices:

Device Family	Product Code	Product Name	End date of extended validity / transition period
Cardiovascular Surgical (Manual Surgical) Devices	1001	Retract-O-Tape - 18 Ga (1.2 mm) tubing, 12in (30.5 cm) long	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	1002	Retract-O-Tape - 16 Ga (1.7mm) tubing , 12in (30.5 cm) long	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	1012	Retract-O-Tape - 16 Ga (1.7mm) tubing, 18in (45.7 cm) long	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	1015	Retract-O-Tape - 10 Ga (3.3mm) tubing, 18in (45.7 cm) long	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	1032	Retract-O-Tape - 16 Ga, (1.7mm) tubing, 18in (45.7 cm) long	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	1041	Retract-O-Tape - 18 Ga (1.2mm) tubing, 12in (30.5 cm) long, 18 Ga blunt needle	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	1071	Retract-O-Tape - 18 Ga (1.2mm) tubing, 12in (30.5 cm) long, 18 Ga semi-pointed needle	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	1541	SaddleLoop® 18 Ga. blunt needle Retract-O-Tape w/ tensioner, 4 in (10cm) long	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	1571	SaddleLoop® 18 Ga. R-O-T w/ tensioner, semi-pointed needle, 4 in (10 cm) long	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	RCC-28	CleanCut® Aortic Punch, 2.8 mm tip	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	RCC-35	CleanCut® Aortic Punch, 3.5 mm tip	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	RCC-40	CleanCut® Aortic Punch, 4.0 mm tip	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	RCC-45	CleanCut® Aortic Punch, 4.5 mm tip	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	RCC-48	CleanCut® Aortic Punch, 4.8 mm tip	2028-12-31



Cardiovascular Surgical (Manual	RCC-50	CleanCut® Aortic Punch, 5.0 mm	2028-12-31
Surgical) Devices	DOL 00	tip	0000 40 04
Cardiovascular Surgical (Manual	RCL-28	CleanCut® Aortic Punch, 2.8 mm	2028-12-31
Surgical) Devices	DOL 25	tip	2020 42 24
Cardiovascular Surgical (Manual	RCL-35	CleanCut® Aortic Punch, 3.5 mm	2028-12-31
Surgical) Devices	RCL-40	tip CleanCut® Aortic Punch, 4.0 mm	2028-12-31
Cardiovascular Surgical (Manual	RGL-40	1	2020-12-31
Surgical) Devices Cardiovascular Surgical (Manual	RCL-45	tip CleanCut® Aortic Punch, 4.5 mm	2028-12-31
Surgical) Devices	RGL-45	tip	2020-12-31
Cardiovascular Surgical (Manual	RCL-48	เp CleanCut® Aortic Punch, 4.8 mm	2028-12-31
Surgical) Devices	RGL-40		2020-12-31
Cardiovascular Surgical (Manual	RCL-50	tip CleanCut® Aortic Punch, 5.0 mm	2028-12-31
Surgical) Devices	ROL-30	tip	2020-12-31
Cardiovascular Surgical (Manual	RCB-40	PerfectCut® Aortic Punch, 4.0	2028-12-31
Surgical) Devices	NOD-40	mm bullet tip	2020-12-31
Cardiovascular Surgical (Manual	RCB-45	PerfectCut® Aortic Punch, 4.5	2028-12-31
Surgical) Devices	KGB-43	mm bullet tip	2020-12-31
Cardiovascular Surgical (Manual	RCB-48	PerfectCut® Aortic Punch, 4.8	2028-12-31
Surgical) Devices	NOD-40	bullet tip	2020-12-31
Cardiovascular Surgical (Manual	RCB-50	PerfectCut® Aortic Punch, 5.0	2028-12-31
Surgical) Devices	NOB-30	mm bullet tip	2020-12-01
Cardiovascular Surgical (Manual	CVR-28	Rotating Aortic Punch, 2.8 mm;	2028-12-31
Surgical) Devices	011120	CardioMedical	2020 12 0 1
Cardiovascular Surgical (Manual	CVR-35	Rotating Aortic Punch, 3.5 mm;	2028-12-31
Surgical) Devices		CardioMedical	
Cardiovascular Surgical (Manual	CVR-40	Rotating Aortic Punch, 4.0 mm;	2028-12-31
Surgical) Devices		CardioMedical	
Cardiovascular Surgical (Manual	CVR-45	Rotating Aortic Punch, 4.5 mm;	2028-12-31
Surgical) Devices		CardioMedical	
Cardiovascular Surgical (Manual	CVR-48	Rotating Aortic Punch, 4.8 mm;	2028-12-31
Surgical) Devices		CardioMedical	
Cardiovascular Surgical (Manual	CVR-50	Rotating Aortic Punch, 5.0 mm;	2028-12-31
Surgical) Devices		CardioMedical	
Cardiovascular Surgical (Manual	RCK-40	One PerfectCut® Aortic Punch,	2028-12-31
Surgical) Devices		4.0 mm bullet tip and one Aortic	
		Lancet	



Cardiovascular Surgical (Manual Surgical) Devices	RCK-45	One PerfectCut® Aortic Punch, 4.5 mm bullet tip and one Aortic Lancet	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	RCK-48	One PerfectCut® Aortic Punch, 4.8 mm bullet tip and one Aortic Lancet	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	RCK-50	One PerfectCut® Aortic Punch, 5.0 mm bullet tip and one Aortic Lancet	2028-12-31
Cardiovascular Surgical (Manual Surgical) Devices	ALX-33	Aortotomy Lancet, 3.3mm (lancet only from RCK Systems)	2028-12-31
Cardiovascular Surgical (Perfusion Safety) Devices	4003103	VRV-II Vacuum Relief Valve	2028-12-31
Cardiovascular Surgical (Perfusion Safety) Devices	4003203	VRV-II Vacuum Relief Valve, non-sterile	2028-12-31
Cardiovascular Surgical (Perfusion Safety) Devices	4004103	VRV-IIC Clear Vacuum Relief Valve	2028-12-31
Cardiovascular Surgical (Perfusion Safety) Devices	4004203	VRV-IIC Clear Vacuum Relief Valve, non-sterile	2028-12-31
Cardiovascular Surgical (Perfusion Safety) Devices	4007100	RetroGuard® Arterial Safety Valve	2028-12-31
Cardiovascular Surgical (Perfusion Safety) Devices	4007200	RetroGuard® Arterial Safety Valve, non-sterile	2028-12-31
Cardiovascular Surgical (Perfusion Safety) Devices	4103102	RLV-2100 "B" Vacuum Relief Valve	2028-12-31
Cardiovascular Surgical (Perfusion Safety) Devices	4103202	RLV-2100 "B" Vacuum Relief Valve, non-sterile	2028-12-31
Cardioplegia Catheters and Perfusion Sets	VCC-03	Vessel Cannula, 3mm (saphenous vein cannula)	2028-12-31
Fluid Delivery Devices	3150	Q2® Needleless injection site	2028-12-31
Fluid Delivery Devices	9520	7 in (18cm) Y-Extension Set w/ 2 check valves	2028-12-31
Fluid Delivery Devices	95701	7 in (18 cm) Q2 T connector Extension Set w/ Q2 T-site- checkvalve, microbore tubing	2028-12-31
Fluid Delivery Devices	95702	10 in (25 cm) Q2 T connector extension set w/ 3 Q2 checkvalve T-sites	2028-12-31



Fluid Delivery Devices	95707	4 in (10 cm) Q2 T-connector extension set, 2 Q2 T-sites without checkvalves, in-line checkvalve, microbore tubing	2028-12-31
Fluid Delivery Devices	95710	12.5 in (32 cm) Q2 T-extension set w/ 3 Q2 checkvalve T-sites, in-line checkvalve, microbore tubing & pinch clamp	2028-12-31
Fluid Delivery Devices	95712	Q2 Multiport Extension Set	2028-12-31
Manual Ophthalmic Surgical Instruments	DCP213-UNIT	LacriCATH Lacrimal Duct Catheter, 2mm Unilateral Procedure Kit	2028-12-31
Manual Ophthalmic Surgical Instruments	DCP213-BIT	LacriCATH Lacrimal Duct Catheter, 2mm Bilateral Procedure Kit	2028-12-31
Manual Ophthalmic Surgical Instruments	DCP315-UNIT	LacriCATH Lacrimal Duct Catheter, 3mm Unilateral Procedure Kit	2028-12-31
Manual Ophthalmic Surgical Instruments	DCP315-BIT	LacriCATH Lacrimal Duct Catheter, 3mm Bilateral Procedure Kit	2028-12-31
Manual Ophthalmic Surgical Instruments	DCR508-UNIT	LacriCATH Lacrimal Duct Catheter, 5mm Unilateral Procedure Kit	2028-12-31
Manual Ophthalmic Surgical Instruments	DCR508-BIT	LacriCATH Lacrimal Duct Catheter, 5mm Bilaterial Procedure Kit	2028-12-31
Manual Ophthalmic Surgical Instruments	LDC213T	LacriCATH Lacrimal Duct Catheter, Balloon Catheter, 2.0/3.0 mm	2028-12-31
Manual Ophthalmic Surgical Instruments	LDC315T	LacriCATH Lacrimal Duct Catheter, Balloon Catheter, 2.0/3.0mm	2028-12-31
Manual Ophthalmic Surgical Instruments	LDC508T	LacriCATH Lacrimal Duct Catheter, Balloon Catheter, 5mm	2028-12-31
Manual Ophthalmic Surgical Instruments	LIS052	STENTube Lacrimal Intubation Set	2028-12-31
Manual Ophthalmic Surgical Instruments	LIS27T	STENTube Lacrimal Intubation Set	2028-12-31



MPS 2 Myocardial Protection System	5001001	MPS Hypothermic Reservoir	2028-12-31
MPS 2 Myocardial Protection System	5001002	MPS Hypothermic Reservoir Holder	2028-12-31
MPS 2 Myocardial Protection System	5001003	MPS Hypothermic Reservoir Hoses	2028-12-31
MPS 2 Myocardial Protection System	5001005	MPS Stand Alone Cart	2028-12-31
MPS 2 Myocardial Protection System	5001023	MPS Console Pole Mount Adapter (Terumo HLM)	2028-12-31
MPS 2 Myocardial Protection System	5001025	MPS Console Adapter, base mount (Terumo HLM)	2028-12-31
MPS 2 Myocardial Protection System	5001030	MPS Heater Cooler Hose Kit	2028-12-31
MPS 2 Myocardial Protection System	5001032	MPS 2 Locking Block Conversion Kit	2028-12-31
MPS 2 Myocardial Protection System	5001100	MPS Delivery Set, no cassettes, w 106 cm inlet	2028-12-31
MPS 2 Myocardial Protection System	5001102	MPS Delivery Set (w/ heat exchanger, arrest & additive cassettes, 3m extension lines)	2028-12-31
MPS 2 Myocardial Protection System	5001102AS	MPS Delivery Set w/ shorter (1.8 m) ext. lines	2028-12-31
MPS 2 Myocardial Protection System	5001103	MPS Delivery Set, with AA, 183 cm Extension line	2028-12-31
MPS 2 Myocardial Protection System	5001104	MPS Arrest Agent Cassette	2028-12-31
MPS 2 Myocardial Protection System	5001105	MPS Additive Cassette	2028-12-31
MPS 2 Myocardial Protection System	5001106	MPS Extension Line	2028-12-31
MPS 2 Myocardial Protection System	5001108	MPS Antegrade / Retrograde Y Set	2028-12-31
MPS 2 Myocardial Protection System	5001110	MPS Water Circuit Adapter	2028-12-31
MPS 2 Myocardial Protection System	5051101	MPS Retrograde Extension Pressure Line, with Pressure Transducer)	2028-12-31



MPS 2 Myocardial Protection System	5051102	MPS Retrograde Extension Pressure Line with Y-set and Pressure Transducer	2028-12-31
MPS 2 Myocardial Protection System	5051103	MPS Pressure line with Transducer	2028-12-31
MPS 2 Myocardial Protection System	5051107	MPS Dual Lumen Retrograde Ext Line with Y-set, no Transducer	2028-12-31
MPS 2 Myocardial Protection System	511700A	MPS Aortic Root Transducer Interface Cable	2028-12-31
MPS 2 Myocardial Protection System	511700R	MPS Coronary Sinus Transducer Interface Cable	2028-12-31
MPS 2 Myocardial Protection System	5140004	MPS Pole Mount Transducer Holder	2028-12-31
MPS 2 Myocardial Protection System	5161102	MPS Delivery Set 16C w/AA 305cm Line	2028-12-31
MPS 2 Myocardial Protection System	520CE16	MPS2 Power Cord - Europe	2028-12-31
MPS 2 Myocardial Protection System	520IT16	MPS2 Italian Power Cord	2028-12-31
MPS 2 Myocardial Protection System	7001101	MPS Mini-Prime Del Set with AA cass	2028-12-31
MPS 2 Myocardial Protection System	7001102	MPS Low Volume Del Set with AA cass	2028-12-31
MPS 2 Myocardial Protection System	7001103	MPS Low Vol Ext 4.8mm x 1.8M	2028-12-31
MPS 2 Myocardial Protection System	7001104	MPS Low Vol Ext (2.0mm x 1.8M)	2028-12-31
MPS 3 Myocardial Protection System	5302000	MPS 3 Console, 200-240V	2028-12-31
MPS 3 Myocardial Protection System	5301000ND	MPS 3 ND Console	2028-12-31
MPS 3 Myocardial Protection System	5303000	MPS 3 Controller	2028-12-31
MPS 3 Myocardial Protection System	5303007	MPS 3 Controller Articulating Mounting Arm	2028-12-31
MPS 3 Myocardial Protection System	5303008	MPS 3 Controller Telescoping Mounting Arm	2028-12-31
MPS 3 Myocardial Protection System	530CE16	MPS 3 Power cord, Continental Europe	2028-12-31



MPS 3 Myocardial Protection	530IT16	MPS 3 Power cord, Italy	2028-12-31
System			
MPS 3 Myocardial Protection	530UK16	MPS 3 Power cord, United	2028-12-31
System		Kingdom	
MPS 3 Myocardial Protection	5301023	MPS 3 Console Pole Mount	2028-12-31
System		Will C o Contone I die Medit	
MPS 3 Myocardial Protection	5301025	MPS 3 Console Adapter	2028-12-31
System		·	
MPS 3 Myocardial Protection	513PWCC-10	MPS 3 UI Power Communication	2028-12-31
System		Cable	
MPS 3 Myocardial Protection	5001001G	MPS Hypothermic Reservoir	2028-12-31
System	500,4000	· · · · · · · · · · · · · · · · · · ·	2000 40 04
MPS 3 Myocardial Protection	5001002	MPS Hypothermic Reservoir	2028-12-31
System	5001110	Holder	2000 40 04
MPS 3 Myocardial Protection	5001110	MPS Water Circuit Adapter	2028-12-31
System	201001	· ·	0000 40 04
MPS 3 Myocardial Protection	801221	MPS Water Hose Connector Kit	2028-12-31
System  MPS 3 Myocardial Protection	F303030		2020 42 24
	5303030	MPS 3 ND Water Hose Kit	2028-12-31
System  MPS 3 Myocardial Protection	5303010		2028-12-31
System	5303010	MPS 3 Medical Air Hose Kit	2020-12-31
MPS 3 Myocardial Protection	513UDMS		2028-12-31
System	3130DIVIS	MPS 3 USB UDMS Cable	2020-12-31
MPS 3 Myocardial Protection	513USCC		2028-12-31
System	3130300	MPS 3 RS232 Cable	2020-12-31
MPS 3 Myocardial Protection	513UECG		2028-12-31
System	3130200	MPS 3 ECG Cable	2020-12-01
MPS 3 Myocardial Protection	513UEXT		2028-12-31
System	0.002,	MPS 3 ECG Extension Cable	2020 12 01
MPS 3 Myocardial Protection	513USPT		2028-12-31
System		MPS 3 ECG Splitter	
MPS 3 Myocardial Protection	5140004	T	2028-12-31
System		Transducer Holder	
MPS 3 Myocardial Protection	511800A	Aortic Root Transducer Interface	2028-12-31
System		Cable (Antegrade)	
MPS 3 Myocardial Protection	511800R	Coronary Sinus Transducer	2028-12-31
System		Interface Cable (Retrograde)	



MPS 3 Myocardial Protection System	5003100	MPS 3 Delivery Set w/183cm (10C)	2028-12-31
MPS 3 Myocardial Protection System	5ND3100	MPS 3 ND Delivery Set w/o AA w/305cm Line (16C)	2028-12-31
MPS 3 Myocardial Protection System	5003102	MPS 3 Delivery Set w/AA w/305cm Line	2028-12-31
MPS 3 Myocardial Protection System	5ND3102	MPS 3 ND Delivery Set w/AA w/305cm Line (16C)	2028-12-31
MPS 3 Myocardial Protection System	5003102-AS	MPS 3 Delivery Set w/AA w/183 Line (10C)	2028-12-31
MPS 3 Myocardial Protection System	5ND3102-AS	MPS 3 ND Delivery Set w/AA w/183 Line (16C)	2028-12-31
MPS 3 Myocardial Protection System	5003103	MPS 3 Delivery Set w/AA w/106cm (10C)	2028-12-31
MPS 3 Myocardial Protection System	5ND3103	MPS 3 ND Delivery Set w/AA w/106cm (16C)	2028-12-31
MPS 3 Myocardial Protection System	5003104	MPS 3 Arrest Cartridge	2028-12-31
MPS 3 Myocardial Protection System	5003105	MPS 3 Additive Cartridge	2028-12-31
MPS 3 Myocardial Protection System	5053106	MPS 3 Arrest Agent Delivery Line	2028-12-31
MPS 3 Myocardial Protection System	5053107	MPS 3 Additive Delivery Line	2028-12-31
MPS 3 Myocardial Protection System	7003101	MPS 3 Mini Prime Delivery Set	2028-12-31
MPS 3 Myocardial Protection System	7003102	MPS 3 Mini Prime Delivery Set	2028-12-31
MPS 3 Myocardial Protection System	5163100	MPS 3 Delivery Set w/183cm (16C)	2028-12-31
MPS 3 Myocardial Protection System	5163102	MPS 3 Delivery Set w/AA w/305cm Line (16C)	2028-12-31
MPS 3 Myocardial Protection System	5163102-AS	MPS 3 Delivery Set w/AA w/183 Line (16C)	2028-12-31
MPS 3 Myocardial Protection System	5163103	MPS 3 Delivery Set w/AA w/106cm (16C)	2028-12-31
MPS 3 Myocardial Protection System	5301016	MPS 3 Blood Bypass Tubing	2028-12-31



MPS 3 Myocardial Protection System	5001106	3/16" x 10ft. (120") Extension Line	2028-12-31
MPS 3 Myocardial Protection System	7001103	3/16" x 6ft. (72") Extension Line	2028-12-31
MPS 3 Myocardial Protection System	5001108	Antegrade/Retrograde Y-Set	2028-12-31
MPS 3 Myocardial Protection System	5051101	Retrograde Extension Pressure Line with Transducer	2028-12-31
MPS 3 Myocardial Protection System	5051102	Retrograde Extension Pressure Line with Transducer and Y-Set	2028-12-31
MPS 3 Myocardial Protection System	5051103	Pressure Line with Transducer	2028-12-31
MPS 3 Myocardial Protection System	5051107	Dual Lumen Retrograde Extension Line with Y-Set	2028-12-31