

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

This is a declaration made in accordance with the requirements of the European Council Directive 93/42/EEC of 14th June 1993, concerning medical devices (MDD)

Manufacturer	ICU Medical, Inc.
Business Address:	951 Calle Amanecer, San Clemente, California 92673 USA
EU Authorized Representative:	Medical Device Safety Service, GmbH (MDSS) Schiffgraben 41 D-30175 Hannover, Germany
Medical Devices: Identification of object of the declaration:	List numbers and descriptions are included in Attachment A of this document
MDD Classification:	Class IIa Rule 2 according to Annex IX of the MDD Class IIb Rule 10 according to Annex IX of the MDD

Statement of Conformity:

We, ICU Medical, Inc. solely declare that the above products, described herein, comply with the Essential Requirements and applicable provisions of the Council Directive 93/42/EEC of 14th June 1993, concerning medical devices and the transitional provisions of (EU) 2017/745 Article 120(3).

This declaration is based on:

Devices are certified according to Annex II, Section 3.2 of the council Directive 93/42/EEC of 14th June 1993, concerning medical devices.

EC Certificate Number: 252.702

Product Scope: Disposable Pressure Monitoring Devices, Kits, and Accessories

Notified Body: National Standards Authority of Ireland (NSAI)
1 Swift Square, Northwood, Santry,
Dublin 9, Ireland

Notified Body Number: 0050

Authorised Signatory:

Issuers Name: Vimala Punsammy
Dept: Global Device Regulatory Affairs


Signature

05/01/2023
Date

Place of Issue: San Clemente, California

Date of Issue: 05/01/2023

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PN	Description	Classification, Rule	GMDN Code
011-41412-01	THERMOSET® ROOM TEMPERATURE CLOSED LOOP INJECTATE DELIVERY SYSTEM	Class IIa, Rule 2	44833
011-41422-16	THERMOSET® IN-LINE THERMISTOR PROBE	Class IIa, Rule 2	44833
011-41422-27	THERMOSET™ IN-LINE THERMISTOR PROBE	Class IIa, Rule 2	44833
011-41422-42	THERMOSET™ IN-LINE THERMISTOR PROBE	Class IIa, Rule 2	44833
011-41423-01	ICED THERMOSET™ CLOSED- LOOP INJECTATE DELIVERY SYSTEM FOR COLD INJECTATE	Class IIa, Rule 2	44833
011-41423-03	ICED THERMOSET® CLOSED-LOOP INJECTATE DELIVERY SYSTEM FOR COLD INJECTATE	Class IIa, Rule 2	44833
011-41424-03	THERMOSET® ROOM TEMPERATURE CLOSED-LOOP INJECTABLE DELIVERY SYSTEM WITH IN-LINE TEMPERATURE PROBE	Class IIa, Rule 2	44833
011-41425-01	THERMOSET FLOW-THROUGH HOUSING	Class IIa, Rule 2	44833
MONITORING KIT AND ASSOCIATED DEVICES PRODUCT CODES (EXCEPT THERMOSET)			
011-0D983-01	Arterial Pressure Tubing - MM 36" (91 cm)	Class IIa, Rule 2	35529
011-0E066-01	LATEX-FREE MONITORING STOPCOCK EXTENSION SET	Class IIa, Rule 2	32172
011-0E069-01	DOUBLE MALE LUER LOCK	Class IIa, Rule 2	60538
011-0E519-01	ACCUDYNAMIC DAMPING DEVICE	Class IIa, Rule 2	63613
011-0F877-01	ARTERIAL PRESSURE TUBING -SL, 6 INCH (15 CM)	Class IIa, Rule 2	35529
011-0F878-01	ARTERIAL PRESSURE TUBING - SL 12 INCHES (30 CM)	Class IIa, Rule 2	35529
011-0F879-01	ARTERIAL PRESSURE TUBING - SL 24 INCH (60 CM)	Class IIa, Rule 2	35529
011-0F880-01	ARTERIAL PRESSURE TUBING - SL 36 INCHES (90 CM)	Class IIa, Rule 2	35529
011-0F881-01	ARTERIAL PRESSURE TUBING - SL 48 INCHES (120 CM)	Class IIa, Rule 2	35529
011-0F882-01	ARTERIAL PRESSURE TUBING - SL 60 INCHES (152 CM)	Class IIa, Rule 2	35529
011-0F883-01	ARTERIAL PRESSURE TUBING- SL 72 INCHES (182 CM)	Class IIa, Rule 2	35529
011-0F884-01	ARTERIAL PRESSURE TUBING - SL 84 INCHES (213 CM)	Class IIa, Rule 2	35529
011-0H120-01	80 CM ARTERIAL PRESSURE TUBING Male/Male	Class IIa, Rule 2	35529
011-0H138-01	Transpac® IV Bifurcated Monitoring Kit, 72" (182cm) Tubing, 2 3 ml Squeeze Flush, 2 Disposable Transducers, Macro drip	Class IIb, Rule 10	45275
011-0H231-01	Stopcock with 6" (15 cm) Red Stripe Pressure Tubing	Class IIa, Rule 2	32172
011-0H300-01	Transpac® IV Monitoring Kit with 2 Stopcocks	Class IIb, Rule 10	45275
011-0H411-01	BLUNTED CANNULA FOR USE WITH SAFESET	Class IIa, Rule 2	45760
011-0H453-01	Transpac® IV Monitoring Kit with Stopcock	Class IIb, Rule 10	45275
011-0H687-01	Transpac® IV Bifurcated Monitoring Kit, 48" (122 cm) Tubing, 2 3 ml Squeeze Flush, 2 Disposable Transducers, Macro drip	Class IIb, Rule 10	45275
011-0H763-01	Cath Lab Kit with 3 Station Manifold and 2 Admin Sets	Class IIa, Rule 2	16545
011-0H796-01	CVP RA Proximal Blue line with Stopcock and Pressure Tubing	Class IIa, Rule 2	35529
011-0H803-01	3 Station Manifold W/ Patient Line (8"/ 20 cm pressure tubing)	Class IIa, Rule 2	16545
011-0H825-01	150 CM ARTERIAL PRESSURE TUBING	Class IIa, Rule 2	35529
011-0H834-01	Cath Lab Kit with 4 Stopcocks, Admin Set, and 2-way connector	Class IIa, Rule 2	16545
011-0H876-01	Transpac® IV Monitoring Kit with 2 Stopcocks	Class IIb, Rule 10	45275
011-0H895-01	Cath Lab Kit with 3 Station Manifold and 2 Admin Sets	Class IIa, Rule 2	16545

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Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-OJ069-01	Transpac® IV Monitoring Kit, 36" (91 cm) Tubing, 30 ml Intraflo Flush, Stopcock	Class IIb, Rule 10	45275
011-OJ153-01	Transpac® IV MONITORING KIT, 12" (30 cm) TUBING, 3 ml SQUEEZE FLUSH, DISPOSABLE TRANSDUCER, MACRODRIP	Class IIb, Rule 10	45275
011-OJ293-01	Custom PT For Abbott Switzerland 183 cm Male-Male SWI 056 Critical Care Custom Product	Class IIa, Rule 2	16545
011-OJ387-01	Transpac® IV With 2 3 Way Stopcocks, 72" (182 cm) Tubing, Disposable Transducer	Class IIb, Rule 10	45275
011-OJ475-01	Transpac® IV Trifurcated Monitoring Kit, 48" (122 cm) Tubing, 3 3 ml Squeeze Flush, 3 Disposable Transducers, 3 Stopcocks, Macrodrrip	Class IIb, Rule 10	45275
011-OJ553-01	Cath Lab Kit with 4 Station Manifold, Bag spike, Vented Piercing Pin, Waste System, Angiographic Syringe, and extension tubing	Class IIa, Rule 2	16545
011-OJ725-01	Transpac® IT Monitoring Kit with 2 Red Stopcocks and Separate Blue Line with Stopcock	Class IIb, Rule 10	45275
011-OJ726-01	Transpac® IT Monitoring Kit, 60" (152cm) Tubing, Stopcock, Bag Spike 27-0218	Class IIb, Rule 10	45275
011-OJ727-01	Transpac® IT Monitoring Kit, 152cm Tubing, 3 Stopcocks, Macrodrrip	Class IIb, Rule 10	45275
011-OJ729-01	Single Transpac® IT Monitoring Kit w/ 104" (264 cm) Red Stripe Tubing	Class IIb, Rule 10	45275
011-OJ730-01	Single Transpac® IT Monitoring Kit w/ 48" (122 cm) Tubing and stopcock	Class IIb, Rule 10	45275
011-OJ731-01	TPIT SINGLE MONITORING KIT W/Safeset® Reservoir and blood port, Stopcock, Macrodrrip	Class IIb, Rule 10	45275
011-OJ732-01	Transpac® IT Monitoring Kit w/ 152cm Tubing, stopcock, macrodrrip	Class IIb, Rule 10	45275
011-OJ734-01	Transpac® IT Bifurcated Monitoring Kit, 152cm Tubing, 2 3ml Flushes, 2 Disposable Transducers, 2 Stopcocks, Macrodrrip	Class IIb, Rule 10	45275
011-OJ735-01	Transpac® IT Trifurcated Monitoring Kit, 152cm Tubing, 3 3ml Flushes, 3 Disposable Transducers, 3 Stopcocks, Macrodrrip	Class IIb, Rule 10	45275
011-OJ736-01	Transpac® IT Monitoring Kit w/ 72" (182cm) Tubing, 2 Stopcocks, Admin Set	Class IIb, Rule 10	45275
011-OJ738-01	Transpac® IT Monitoring Kit w/ 152cm Tubing, Macrodrrip	Class IIb, Rule 10	45275
011-OJ741-01	Transpac® IT Monitoring Kit w/ 72" (182cm) Tubing, 2, Stopcocks, Macrodrrip	Class IIb, Rule 10	45275
011-OJ742-01	Transpac® IT Monitoring Kit w/ 152cm Tubing, Stopcock, Macrodrrip, and 15cm extension set with stopcock	Class IIb, Rule 10	45275
011-OJ743-01	Transpac® IT Double Bifurcated Monitoring Kit, 152cm Tubing, 3 3ml Flushes, 3 Disposable Transducers, 6 Stopcocks, Macrodrrip	Class IIb, Rule 10	45275
011-OJ745-01	Transpac® IT Monitoring Kit w/ 64" (162 cm) Tubing, 2 Stopcocks, Macrodrrip	Class IIb, Rule 10	45275
011-OJ749-01	Transpac® IT Monitoring Kit w/ 12" (30 cm) Tubing, 2 Stopcocks	Class IIb, Rule 10	45275
011-OJ751-01	Single Transpac® IT Monitoring Kit w/ Safeset™ Reservoir, 1 Blood Sampling Port and 6 Cannula	Class IIb, Rule 10	45275
011-OJ759-01	Single Transpac® IT Monitoring Kit w/ Safeset™ Reservoir, 2 Blood Sampling Port and 6 Cannula	Class IIb, Rule 10	45275
011-OJ762-01	Bifurcated Monitoring Kit Transpac® IT w/ Safeset™ Reservoir, 2 Blood Sampling Ports and 4 cannula	Class IIb, Rule 10	45275
011-OJ765-01	Single Transpac® IT Monitoring Kit w/ Safeset™ Reservoir, 1 Blood Sampling Port and 10 Cannula	Class IIb, Rule 10	45275
011-OJ769-01	Transpac® IT Monitoring Kit, 9" (22 cm) Tubing, Disposable Transducer (Patient Mount)	Class IIb, Rule 10	45275
011-OJ786-01	Transpac® IT Bifurcated Monitoring Kit, 72" (182cm) Tubing, 2 3ml Flushes, 2 Disposable Transducers, 2 Stopcocks, Admin set	Class IIb, Rule 10	45275
011-OJ789-01	Transpac® IT Trifurcated Monitoring Kit, 30cm Tubing, 3 3ml Flushes, 3 Disposable Transducers, 4 Stopcocks, Macrodrrip	Class IIb, Rule 10	45275
011-OJ792-01	Transpac® IT Bifurcated Monitoring Kit, 69cm Tubing, 1 3ml Flush, 1 Intraflo 3ml, 1 Disposable Transducer, 4 Stopcocks, Admin set	Class IIb, Rule 10	45275

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011-OJ794-01	Transpac® IT Monitoring Kit, 72" (182cm) Tubing, 3 ml Flush Device, Stopcock, Macro drip	Class IIb, Rule 10	45275
011-OJ809-01	Transpac® IT Monitoring Kit, 72" (182cm) Tubing, 3 ml Flush Device, Macro drip	Class IIb, Rule 10	45275
011-OJ810-01	Transpac® IT Bifurcated Monitoring Kit, 24" (60 cm) Tubing, 2 3ml Flushes, 2 Disposable Transducers, 2 Stopcocks, Admin set	Class IIb, Rule 10	45275
011-OJ811-01	Transpac® Trifurcated Monitoring Kit, 60" (152cm) Tubing, 3 3 ml Flush Devices, Macro drip	Class IIb, Rule 10	45275
011-OJ814-01	Transpac® IT Monitoring Kit, 183cm Tubing, 3 ml Flush Device, 2 Stopcock, 152 cm extension set, Macro drip	Class IIb, Rule 10	45275
011-OJ815-01	Transpac® IT Monitoring Kit, 60" (152cm) Tubing, 3 ml Flush Device, Stopcock	Class IIb, Rule 10	45275
011-OJ818-01	Transpac® IT Bifurcated Monitoring Kit, 24" (60 cm) Tubing, 2 3ml Flushes, 2 Disposable Transducers, 2 Stopcocks, Bag Spike	Class IIb, Rule 10	45275
011-OJ819-01	Transpac® IT Trifurcated Monitoring Kit, 10" (12cm) Tubing, 3 3ml Flushes, 3 Disposable Transducers, 5 Stopcocks, Macro drip	Class IIb, Rule 10	45275
011-OJ820-01	Bifurcated Monitoring Kit Transpac® IT w/ Safeset™ Reservoir, Blood Sampling Port, 2 Disposable Transducers, 2 Stopcock, Admin Set	Class IIb, Rule 10	45275
011-OJ842-01	Transpac® IT Monitoring Kit, 60" (152cm) Tubing, Macro drip	Class IIb, Rule 10	45275
011-OJ843-01	Transpac® IT Monitoring Kit, 152cm Tubing, Stopcock, Macro drip	Class IIb, Rule 10	45275
011-OJ844-01	Transpac® IT Monitoring Kit, 152cm Red-stripe Tubing, Stopcock, Macro drip	Class IIb, Rule 10	45275
011-OJ845-01	Transpac® IT Monitoring Kit, 152cm Red-stripe Tubing, Stopcock, 15 cm extension set, Macro drip	Class IIb, Rule 10	45275
011-OJ847-01	Transpac® IT Monitoring Kit, 60" (152cm) Red-stripe Tubing, Stopcock, 60" (152cm) Blue striped extension set, Macro drip	Class IIb, Rule 10	45275
011-OJ859-01	Transpac® IT Bifurcated Monitoring Kit, 61 cm Tubing, 2 3ml Flushes, 2 Disposable Transducers, 2 Stopcocks, Macro drip	Class IIb, Rule 10	45275
011-OJ942-01	Transpac® IT Monitoring Kit, 80" (203 cm) Tubing, 2 Stopcocks, Macro drip (red stipe line)	Class IIb, Rule 10	45275
011-OJ943-01	Transpac® IT Monitoring Kit, 80" (203 cm) Blue striped Tubing, Macro drip	Class IIb, Rule 10	45275
011-OJ944-01	Transpac® IT Monitoring Kit, 203 cm Tubing, 2 Stopcock, rotating male/male, drip chamber	Class IIb, Rule 10	45275
011-OJ945-01	Bifurcated Monitoring Kit Transpac® IT w/ Safeset™ Reservoir, 2 Blood Sampling Ports, 2 stopcocks, 76cm extension set	Class IIb, Rule 10	45275
011-OJ946-01	Transpac® IT Bifurcated Monitoring Kit, 61 cm Tubing, 2 3ml Flushes, 2 Disposable Transducers, 2 Stopcocks, Macro drip (w/ 15cm extension)	Class IIb, Rule 10	45275
011-OJ947-01	Transpac® IT Bifurcated Monitoring Kit, 61 cm Tubing, 2 3ml Flushes, 2 Disposable Transducers, 2 Stopcocks, Macro drip (w/ 12"/30 cm extension)	Class IIb, Rule 10	45275
011-OJ949-01	Transpac® IT Bifurcated Monitoring Kit, 12"/30 cm Tubing, 2 3ml Flushes, 2 Disposable Transducers, 2 Stopcocks, Admin Set	Class IIb, Rule 10	45275
011-OJ950-01	Transpac® IT Bifurcated Monitoring Kit, 12"/30 cm Tubing, 2 3ml Flushes, 2 Disposable Transducers, 4 Stopcocks, Admin Set	Class IIb, Rule 10	45275
011-OJ951-01	Transpac® IT Monitoring Kit, 152cm Tubing, 2 Stopcocks, Macro drip	Class IIb, Rule 10	45275
011-OJ957-01	DOUBLE TP IT MONITORING KIT W/CVP LINE	Class IIb, Rule 10	45275
011-OJ958-01	Transpac® IT Monitoring Kit, 80" (203 cm) Tubing, 3 ml Flush Device, Macro drip	Class IIb, Rule 10	45275
011-OJ959-01	SINGLE TP IT MONITORING KIT RED, 48" (122 cm), 1 stopcock	Class IIb, Rule 10	45275
011-OJ960-01	SINGLE TP IT MONITORING KIT BLUE, 48" (122 cm), 1 stopcock	Class IIb, Rule 10	45275
011-OJ961-01	SINGLE TP IT KIT W/Safeset® AND blue CVP LINE 48" (122 cm), 1 blood port, 3 stopcocks	Class IIb, Rule 10	45275
011-OJ965-01	Transpac® IT Monitoring Kit, 6" (15 cm) Tubing, 30 ml Flush Device	Class IIb, Rule 10	45275
011-OJ966-01	SINGLE TP IT KIT W/Safeset® AND blue CVP LINE 48" (122 cm), 1 blood port, 2 stopcocks	Class IIb, Rule 10	45275

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Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-OJ967-01	Single TP IT Monitoring Kit Blue w/03 ml Flush Device, 72" (182cm) Tubing a	Class IIb, Rule 10	45275
011-OJ972-01	Transpac® Trifurcated Monitoring Kit, 80" (203 cm) Tubing, 3 3 ml Flush Device, Disposable Transducer, Marcodrip	Class IIb, Rule 10	45275
011-OJ973-01	SINGLE TP IT MONITORING KIT W/CVP-LINE 48" (122 cm), 60" (152 cm) line, Spike, 2 Stopcocks	Class IIb, Rule 10	45275
011-OJ974-01	SINGLE TP IT MONITORING KIT W/Safeset®	Class IIb, Rule 10	45275
011-OJ976-01	DOUBLE TP IT MONITORING KIT RED/BLUE Extension line	Class IIb, Rule 10	45275
011-OJ978-01	Transpac® IT Bifurcated Monitoring Kit, 80" (203 cm) Tubing, 2 3ml Flush Device, Macrodrrip	Class IIb, Rule 10	45275
011-OJ980-01	Single TP IT Monitoring Kit W/CVP-Line	Class IIb, Rule 10	45275
011-OJ985-01	SINGLE TP IT MONITORING KIT W/Safeset® Reservoir, 1 blood port, blue line 48" (122 CM) Extension	Class IIb, Rule 10	45275
011-OJ987-01	Transpac® IT Monitoring Kit, 74" (188 cm) Tubing, 30 ml Flush Device	Class IIb, Rule 10	45275
011-OJ988-01	Transpac®Trifurcated Monitoring Kit, 60" (152cm) Tubing, 3 3 ml Flush Device	Class IIb, Rule 10	45275
011-OJ990-01	CUSTOM MONITORING KIT FOR BLACKROCK CLINIC DUBLIN	Class IIb, Rule 10	45275
011-OM242-01	SAFESET SHEILDED CANNULA	Class IIa, Rule 2	45760
011-OM245-01	Safeset® Reservoir with ARTERIAL Pressure Tubing, 2 PORT 152 CM	Class IIa, Rule 2	45760
011-OM246-01	Safeset® Reservoir with ARTERIAL Pressure Tubing 1 PORT 152 CM	Class IIa, Rule 2	45760
011-OM247-01	Safeset® Reservoir with ARTRIAL Pressure Tubing T 1 PORT 60 CM	Class IIa, Rule 2	45760
011-OM273-01	HIGH PRESSURE MANIFOLD, 2 STATION MANIFOLD, RIGHT HAND OFF	Class IIa, Rule 2	16545
011-OM275-01	HIGH PRESSURE MANIFOLD 3 STATION MANIFOLD RIGHT HAND OFF	Class IIa, Rule 2	16545
011-OM279-01	ANGIOGRAPHIC SYRINGE 12ml THUMB RING, (42042-01) ROTATOR RESERVOIR	Class IIa, Rule 2	47017
011-OM280-01	ANGIOGRAPHIC SYRINGE 12ml THUMB RING, (42043-01) FIXED LUER RESERVOIR	Class IIa, Rule 2	47017
011-OM389-01	Safeset® Blunt Cannula 18 GA. X 25 CM (1"/2.5 cm)	Class IIa, Rule 2	45760
011-OM584-01	CLEAR HP TUBING 20" (51 cm)	Class IIa, Rule 2	35529
011-OM866-01	INTRAFLO II PORT 3 ML	Class IIa, Rule 2	45275
011-OP229-01	STD. Transpac®IT MONITORING KIT	Class IIb, Rule 10	45275
011-OP230-01	TRANSDUCER, 60 INCH (152 cm), 3 ml/hr, MICRODRIP	Class IIb, Rule 10	45275
011-OP232-01	TRANSDUCER, 84 INCH (213 CM), 3 ml/hr, MACRODRIP	Class IIb, Rule 10	45275
011-OP235-01	TRANSDUCER 72" INCH (182CM) 3 ML/ HR MACRODRIP	Class IIb, Rule 10	45275
011-OP235-01S	Transducer 72" (182 cm) Red Stripe PT Tubing, 03 ml/hr Flush Device and Macrodrrip	Class IIb, Rule 10	45275
011-OP240-01	1 LINE, 1 TRANSDUCER 72 INCH (182 CM), 3 ML/HR MACRODRIP	Class IIb, Rule 10	45275
011-OP240-01S	Transpac® IT, 3 ML/HR 72" (182 cm) Blue Stripe Pressure Tubing and Macrodrrip	Class IIb, Rule 10	45275
011-OP243-01	TRANSDUCER 9 INCH (23 cm), 3 ml/hr, MACRODRIP PATIENT MOUNT	Class IIb, Rule 10	45275
011-OP244-01	1 LINE, 1 TRANSDUCER 24 INCH (61 CM) 30 ML/HR	Class IIb, Rule 10	45275
011-OP246-01	2 LINES, 2 TRANSDUCERS, 48 INCH (122 cm), 3 ml/hr, MACRODRIP	Class IIb, Rule 10	45275
011-OP247-01	2 LINES, 2 TRANSDUCER, 60 INCH (152 CM), 3 ml/hr, MACRODRIP	Class IIb, Rule 10	45275
011-OP247-01S	2 Lines, 2 Transducer, 60" (152 cm), 3 ml/hr Flush Device, Macrodrrip	Class IIb, Rule 10	45275
011-OP248-01	3 LINE, 3 TRANSDUCERS, 60 INCH (152 CM), 3 ML/HR, MACRODRIP	Class IIb, Rule 10	45275

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011-0P248-01S	3 Line, 3 IT Transpac® Transducers, 60 inch (152 cm), 03 ml/hr Flush Device, Macrodrrip	Class IIb, Rule 10	45275
011-0P260-01	1 TPIT w/1 PAED. Safeset®1 PORT, 48" (122 CM) 30ML/HR	Class IIb, Rule 10	45275
011-0P261-01	1 Safeset® 1 TRANSDUCER 1 PORT, 53 INCH (134 CM), 3ML/ HR MACRODRIP	Class IIb, Rule 10	45275
011-0P264-01	1 Safeset® 1 TRANSDUCER, 1 PORT, 24 INCH (60 cm) 3mL/hr MACRODRIP	Class IIb, Rule 10	45275
011-0P387-01	TRANSDUCER 60" (152 cm) 3 ml/hr MACRODRIP	Class IIb, Rule 10	45275
011-0P400-01	Transpac® IT Bifurcated Monitoring Kit 60" (152cm) Tubing, 2 3ml Flush Device, Macrodrrip	Class IIb, Rule 10	45275
011-0P403-01	Transpac® IT Monitoring Kit 152 cm Tubing, 2 3ml Flush Device, Macrodrrip	Class IIb, Rule 10	45275
011-0P406-01	TP IT MONITORING KIT 30 ML FLUSH	Class IIb, Rule 10	45275
011-0P409-01	Transpac®IT MONITORING KIT, 60" (152cm), 48" (122cm) red line, 1 stopcock	Class IIb, Rule 10	45275
011-0P410-01	Transpac®IT MONITORING KIT, 60" (152cm), 48" (122cm) blue line, 1 stopcock	Class IIb, Rule 10	45275
011-0P414-01	Transpac®IT MONITORING KIT, 60" (152cm), bag spike, 1 stopcock	Class IIb, Rule 10	45275
011-0P415-01	Transpac®IT MONITORING KIT with Safeset, 60" (152cm), bag spike, 1 stopcock, 1 blood port	Class IIb, Rule 10	45275
011-0P428-01	Transpac® IV Trifurcated Monitoring Kit, 60" (152cm) Stripe Tubing, 3 3 ml Flush Device, Macrodrrip	Class IIb, Rule 10	45275
011-0P538-01	KIT HOSPITAL BORDEAUX RP 2VOIES ET VALVES A-RETOUR	Class IIb, Rule 10	45275
011-0P544-01	TP ST MONITORING KIT, 2 stopcock	Class IIb, Rule 10	45275
011-0P545-01	TP ST MONITORING KIT, 72"(183 cm) line with 16"(41cm) extension, 3 stopcock	Class IIb, Rule 10	45275
011-0P552-01	Transpac IT Monitoring Kit, 72" (183cm), 1 stopcock	Class IIb, Rule 10	45275
011-0P555-01	Single Monitoring Line, Transpac®, 60" (152cm) Tubing Macrodrrip, ICP and NO FLUSH DEVICE	Class IIb, Rule 10	35927
011-0P557-01	SINGLE Transpac® WITH 12" (30 cm) TUBING	Class IIb, Rule 10	45275
011-0P559-01	CMK MONASH MED CENTRE -NEONATAL ICP. ST KIT	Class IIb, Rule 10	45275
011-0P560-01	Manifold 2 Port/Off/Right 3-Way, Transpac®IT, 60" (152cm) Admin. Set, 48" (122 cm) PT Tubing	Class IIb, Rule 10	45275
011-0P566-01	TP ST Monitoring Kit, 60" (152cm),, Administration set, 4 stopcocks, 48" (122 CM) red line, 48" (122 CM) blue line extension	Class IIb, Rule 10	45275
011-0P584-01	Cath Lab Kit w/ Transpac ST transducer, 4 Stopcocks	Class IIb, Rule 10	45275
011-0P764-01	DISPOSABLE Transpac®ST TRANSDUCER	Class IIb, Rule 10	45275
011-0P781-01	Admin Set with Male luer	Class IIa, Rule 2	58977
011-0P782-01	Bifurcated Monitoring Kit Transpac®, 2 3-Way Stopcocks, Macrodrrip	Class IIb, Rule 10	45275
011-19704-01	TPIT SINGLE MONITORING KIT (30ML/HR) W/Safeset® BLOOD SAMPLING PORT, NEONATAL PEDIATRIC	Class IIb, Rule 10	45275
011-19705-01	Transpac®IT CVP Single Kit 30 mL/hr w/ 4-way stopcock and rotating adapter luer (blue line)	Class IIb, Rule 10	45275
011-19706-01	Transpac®IT WCH Single Kit 30 mL/hr w/ 4-way stopcock and rotating adapter luer (red line)	Class IIb, Rule 10	45275
011-42005-03	30 ml/hr Continuous Squeeze Flush Device w/4-Way Stopcock	Class IIa, Rule 2	35511
011-42009-01	High Pressure Stopcock, 1000 PSI (68 bar/6.8 MPa) (3-Way, Rotator, Off)	Class IIa, Rule 2	16545
011-42012-03	SINGLE PORT INTRAFLO WITHOUT FILTER, 30 ML/HR CONTINUOUS FLUSH DEVICE	Class IIa, Rule 2	35511
011-42013-03	Single Port Intraflo Without Filter, 03 ml/hr Continuous Flush Device	Class IIa, Rule 2	35511

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PN	Description	Classification, Rule	GMDN Code
011-42014-11	Squeeze Continuous Flush Device, 03 ml/hr	Class IIa, Rule 2	35511
011-42015-01	Squeeze Continuous Flush Device, 30 ml/hr	Class IIa, Rule 2	35511
011-42303-02	SAFESET™ II SHIELDED BLUNT CANNULA	Class IIa, Rule 2	45760
011-42303-12	SAFESET™ II SHIELDED BLUNT CANNULA	Class IIa, Rule 2	45760
011-42304-12	Safeset® 60" (152cm) ARTERIAL PRESSURE TUBING WITH 2 In-Line Safeset® BLOOD SAMPLING PORTS	Class IIa, Rule 2	45760
011-42305-07	Safeset® 27" (68 cm) ARTERIAL PRESSURE TUBING WITH 2 BLOOD SAMPLING PORTS	Class IIa, Rule 2	45760
011-42314-01	2-STATION HIGH PRESSURE STOPCOCK MANIFOLD 600 PSI (41 bar/ 4.1 MPa) (LEFT HAND, OFF HANDLES)	Class IIa, Rule 2	16545
011-42322-02	RESERVOIR SS II 84" (213 cm), AN	Class IIa, Rule 2	45760
011-42322-66	Safeset® 84" (213 cm) Arterial Pressure Tubing, Reservoir and 2 Needleless Valves	Class IIa, Rule 2	45760
011-42322-70	Safeset®84" (213 cm) Arterial Pressure Tubing, Reservoir, and 2 Clave Sampling Ports	Class IIa, Rule 2	45760
011-42323-02	Reservoir, Safeset® II RN 84" (213 cm)	Class IIa, Rule 2	45760
011-42324-02	RESERVOIR Safeset® II AN 60" (152cm)	Class IIa, Rule 2	45760
011-42325-02	RESERVOIR, Safeset® I RN 60"	Class IIa, Rule 2	45760
011-42328-66	24" (60 cm) Safeset® Reservoir w/Needleless Valve	Class IIa, Rule 2	45760
011-42328-70	24" (60 cm) Safeset® Reservoir w/CLAVE Sampling Port	Class IIa, Rule 2	45760
011-42347-20	20 Inch (50 cm) Braided Contrast Media Injection Line	Class IIa, Rule 2	47258
011-42347-48	48" (122 cm) Braided Contrast Media Injection Line	Class IIa, Rule 2	35529
011-42353-01	HIGH PRESSURE STOPCOCK (3-WAY, LUER LOCK, OFF) 600 PSI (41 bar/ 4.1 MPa)	Class IIa, Rule 2	16545
011-42364-01	12" (30 CM) Arterial Pressure Tubing	Class IIa, Rule 2	35529
011-42368-01	36" (91 cm) Arterial Pressure Tubing	Class IIa, Rule 2	35529
011-42369-01	36" (91 cm) Arterial Pressure Tubing Male/Male	Class IIa, Rule 2	35529
011-42370-01	48" (122cm) ARTERIAL PRESSURE TUBING	Class IIa, Rule 2	35529
011-42373-01	60" (152cm) ARTERIAL PRESSURE TUBING MALE/MALE	Class IIa, Rule 2	35529
011-42375-01	72" (182 cm) Arterial Pressure Tubing Male/Male	Class IIa, Rule 2	35529
011-42376-01	84"(213cm) ARTERIAL PRESSURE TUBING	Class IIa, Rule 2	35529
011-42377-01	84" (213 CM) ARTERIAL TUBING MALE/MALE	Class IIa, Rule 2	35529
011-42378-05	Monitoring Kit Administration Set With Macrodrip Chamber	Class IIa, Rule 2	58977
011-42379-11	Monitoring Kit Bifurcated Fluid Administration Set With Microdrip Chamber	Class IIa, Rule 2	58977
011-42381-05	Monitoring Kit Trifurcated Fluid Administration Set With Macrodrip Chamber	Class IIa, Rule 2	58977
011-42381-11	Monitoring Kit Trifurcated Fluid Administration Set With Microdrip Chamber	Class IIa, Rule 2	58977
011-42397-01	High Pressure Stopcock (3-Way, Rotator, Off) 600 PSI (41 bar/ 4.1 MPa)	Class IIa, Rule 2	16545
011-42407-01	3 Inch (7 cm)Monitoring Extension Set (Tubing with Stopcock)	Class IIa, Rule 2	32172
011-42408-11	6 Inch (15 cm) Monitoring Extension Set (Tubing with Stopcock)	Class IIa, Rule 2	32172
011-42412-01	ACCUDYNAMIC®	Class IIa, Rule 2	63613
011-42431-10	10 Inch (25 cm) Clear Contrast Media Injection Line	Class IIa, Rule 2	47258
011-42431-30	30 Inch (76 cm) Clear Contrast Media Injection Line, MAX PRESSURE = 1000 PSI (68 bar/6.8 MPa)	Class IIa, Rule 2	47258

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-42500-01	BRIDGE ADD-ON 2 3-WAY STOPCOCKS JOINED BY A Male/Male CONNECTOR	Class IIa, Rule 2	32172
011-42500-02	Transpac® IV MONITORING KIT WITH 2 BONDED STOPCOCKS, 72" (182cm), DISPOSABLE TRANSDUCER WITH 2 BONDED STOPCOCKS, 3 ML SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42500-03	Transpac® IV DISPOSABLE TRANSDUCER WITH STOPCOCKS	Class IIb, Rule 10	45275
011-42500-04	Transpac® IV TRIFURCATED KIT WITH Safeset® RESERVOIR AND 2 BLOOD SAMPLING PORTS, 84" (213 cm) TUBING, 3 3 ml INTRAFLO® FLUSHES, 3 DISPOSABLE TRANSDUCERS, MACRODRIP	Class IIb, Rule 10	45275
011-42500-06	Transpac® IV BIFURCATED KIT WITH Safeset® RESERVOIR AND BLOOD SAMPLING PORTS, 84" (213 cm) TUBING, 2 SQUEEZE FLUSHES, 2 DISPOSABLE TRANSDUCERS, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42500-19	Transpac® IV BIFURCATED KIT MONITORING, 72" (182cm) 2 DISPOSABLE TRANSDUCERS, WITH 2 STOPCOCKS, 2 3 ML SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42500-22	Transpac® IV BIFURCATED MONITORING KIT WITH Safeset® RESERVOIR AND 2 BLOOD SAMPLING PORTS, 84" (213 cm) TUBING, 2 INTRAFLO® FLUSHES, 2 DISPOSABLE TRANSDUCERS, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42500-66	Transpac® IV Bifurcated Kit w/Safeset® Reservoir, 03 ml Squeeze Flush and Needleless Valves	Class IIb, Rule 10	45275
011-42500-70	Transpac® IV Bifurcated Kit w/84" (213 cm) Safeset® Reservoir, 03 ml Squeeze Flush Device and 2 Clave Sampling Ports	Class IIb, Rule 10	45275
011-42552-02	Safeset® Neonatal/Pediatric Kit, Safeset® Reservoir and Blood Sampling Port	Class IIa, Rule 2	45760
011-42554-02	Transpac® IV MONITORING KIT WITH Safeset® RESERVOIR AND BLOOD SAMPLING PORT, NEONATAL/PEDIATRIC KIT, 30 ML INTRAFLO® FLUSH, DISPOSABLE TRANSDUCER	Class IIb, Rule 10	45275
011-42582-05	Transpac® IV Disposable Transducer	Class IIb, Rule 10	45275
011-42582-06	Transpac® IV DISPOSABLE TRANSDUCER WITH STOPCOCKS	Class IIb, Rule 10	45275
011-42582-08	Transpac® IV DISPOSABLE TRANSDUCER WITH 4 FT. CABLE EXTENSION AND STOPCOCK	Class IIb, Rule 10	45275
011-42582-09	Transpac® IV Disposable Transducer Monitoring Kit w/Bonded Stopcock and 3mL Squeeze Flush Device	Class IIb, Rule 10	45275
011-42583-01	Transpac® IV MONITORING KIT DISPOSABLE TRANSDUCER, 3 ML SQUEEZE FLUSH, MACRODRIP (INTENDED FOR PATIENT MOUNT)	Class IIb, Rule 10	45275
011-42583-05	Transpac® IV MONITORING KIT DISPOSABLE TRANSDUCER, 3 ML SQUEEZE FLUSH, MACRODRIP (INTENDED FOR PATIENT MOUNT)	Class IIb, Rule 10	45275
011-42583-06	Transpac® IV DISPOSABLE TRANSDUCER WITH STOPCOCKS	Class IIb, Rule 10	45275
011-42584-05	Transpac® IV MONITORING KIT, DISPOSABLE TRANSDUCER, 3 ML SQUEEZE FLUSH, MACRODRIP	Class IIb, Rule 10	45275
011-42584-09	Transpac® IV MONITORING KIT DISPOSABLE TRANSDUCER WITH BONDED STOPCOCK, 3 ML SQUEEZE FLUSH, MACRODRIP, 60" (152cm), DISPOSABLE TRANSDUCER WITH BONDED STOPCOCK, 3 ml SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42585-05	Transpac® IV Monitoring Kit, 84" (213 cm), Disposable Transducer, 03 ml Squeeze Flush Device, Macrodrrip	Class IIb, Rule 10	45275
011-42586-05	Transpac® IV MONITORING KIT NEONATAL, 24" (60 cm), DISPOSABLE TRANSDUCER, 30 ML SQUEEZE FLUSH (INFUSION PUMP)	Class IIb, Rule 10	45275
011-42587-05	Transpac® IV MONITORING KIT 60 INCH (152 cm), DISPOSABLE TRANSDUCER, 3 ML INTRAFLO® FLUSH AND MACRODRIP	Class IIb, Rule 10	45275
011-42588-05	Transpac® IV MONITORING KIT, NEONATAL, 24" (60 cm), WITH DISPOSABLE TRANSDUCER, 30 ML INTRAFLO® FLUSH (INFUSION PUMP)	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-42589-05	Transpac® IV MONITORING KIT, 9" (17 cm), DISPOSABLE TRANSDUCER, 3 ML INTRAFLO® FLUSH, MACRODRIP (PATIENT MOUNT)	Class IIb, Rule 10	45275
011-42590-05	Transpac® IV TRIFURCATED MONITORING KIT 60 INCH (152 cm), 3 DISPOSABLE TRANSDUCERS, 3 3 ML SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42590-08	Transpac® IV TRIFURCATED MONITORING KIT 84" (213 cm), 3 DISPOSABLE TRANSDUCERS WITH 2 STOPCOCKS 3 3 ML SQUEEZE FLUSHES, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42591-05	Transpac® IV TRIFURCATED MONITORING KIT 60" (152cm), 3 DISPOSABLE TRANSDUCERS, 3 3 ML INTRAFLO® FLUSHES, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42592-01	Transpac® IV BIFURCATED MONITORING KIT 48" (122 cm), 2 DISPOSABLE TRANSDUCERS, 2 3 ML INTRAFLO® FLUSHES, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42592-05	Transpac® IV BIFURCATED MONITORING KIT 48" (122 cm), 2 DISPOSABLE TRANSDUCERS, 2 3 ML INTRAFLO® FLUSHES, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42594-05	Transpac® IV Monitoring Kit w/4 Way Stopcock, 3 Way Stopcock and 24" (60 cm) Arterial Pressure Tubing	Class IIb, Rule 10	45275
011-42597-05	Transpac® IV BIFURCATED MONITORING KIT 48" (122 cm), 2 DISPOSABLE TRANSDUCERS, 2 3 ML SQUEEZE FLUSHES, MACRODRIP, (POLE MOUNT)	Class IIb, Rule 10	45275
011-42598-01	Monitoring Kit w/TP4, 30 ml Squeeze Flush and Needleless Valve	Class IIb, Rule 10	45275
011-42598-70	Transpac® IV Monitoring Kit w/30 ml Squeeze Flush Device, 10 ml Syringe Contamination Sheath and Clave Sampling Port	Class IIb, Rule 10	45275
011-42606-05	Transpac® IV MONITORING KIT WITH DISPOSABLE TRANSDUCER, 3 ML INTRAFLO® FLUSH AND MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42607-01	Transpac® IV MONITORING KIT, 60" (152cm), DISPOSABLE TRANSDUCER, 3 ML SQUEEZE FLUSH, MICRODRIP® (POLE MOUNT)	Class IIb, Rule 10	45275
011-42607-05	Transpac® IV MONITORING KIT, 60" (152cm), DISPOSABLE TRANSDUCER, 3 ML SQUEEZE FLUSH, MICRODRIP® (POLE MOUNT)	Class IIb, Rule 10	45275
011-42620-08	Transpac® IV Monitoring Kit with 2 Safeset® Blood Sampling Ports, 60" (152cm) Tubing, Disposable Transducer, 3 ml Squeeze Flush, Macrodrrip (Pole Mount)	Class IIb, Rule 10	45275
011-42632-05	Transpac® IV Monitoring Kit, 72" (182cm), Disposable Transducer, 03 ml Squeeze Flush Device, Macrodrrip (POLE MOUNT)	Class IIb, Rule 10	45275
011-42634-05	Transpac® IV Monitoring Kit Neonatal, 12" (30 cm), 3 Stopcocks, Disposable Transducer, 30 ml Squeeze Flush (For Use with Infusion Pump)	Class IIb, Rule 10	45275
011-42640-06	Transpac® IV Monitoring Kit With Safeset® Reservoir and Blood Sampling Port, 60" (152cm) Tubing, Disposable Transducer, 3 ml Squeeze Flush, Macrodrrip (Pole Mount)	Class IIb, Rule 10	45275
011-42640-70	Transpac IV Monitoring Kit w/03 ml Flush Squeeze Device, 84" (213 cm) Safeset Reservoir and Clave Sampling Port	Class IIb, Rule 10	45275
011-42644-06	Transpac® IV MONITORING KIT WITH Safeset® RESERVOIR AND 2 BLOOD SAMPLING PORTS, 60" (152cm) TUBING, DISPOSABLE TRANSDUCER, 3 ML SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42644-66	Transpac® IV Monitoring Kit w/Safeset® 60" (152cm) Arterial Pressure Tubing, Reservoir, 03 ml Squeeze Flush and 2 Needleless Valves	Class IIb, Rule 10	45275
011-42644-70	Transpac® IV Monitoring Kit w/60" (152cm) Safeset® Reservoir, 03 ml Squeeze Flush Device and 2 Clave Sampling Port	Class IIb, Rule 10	45275
011-42646-06	Transpac® IV MONITORING KIT WITH Safeset® RESERVOIR AND 2 BLOOD SAMPLING PORTS, 84" (213 cm) TUBING, DISPOSABLE TRANSDUCER, 3 ML SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42646-66	Transpac® IV Monitoring Kit w/Safeset® 84" (213 cm) Arterial Pressure Tubing, Reservoir, Squeeze Flush and 2 Needleless Valves	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-42648-06	Transpac® IV Monitoring Kit w/ Safeset® Reservoir and Blood Sampling Port, 24" (60 cm) Tubing, Disposable Transducer, 03 ml Squeeze Flush, Macrodrrip (Patient Mount)	Class IIb, Rule 10	45275
011-42648-66	Transpac® IV Monitoring Kit w/ Safeset® Reservoir, Needleless Valve, 24" (60 cm) Tubing, Disposable Transducer, 03 ml Squeeze Flush, Macrodrrip (Patient Mount)	Class IIb, Rule 10	45275
011-42648-70	Transpac® IV Monitoring Kit w/24" (60 cm) Safeset® Reservoir, Clave Sampling port, 03 ml Squeeze Flush Device, Macrodrrip (Patient Mount)	Class IIb, Rule 10	45275
011-42649-06	Transpac® IV MONITORING KIT WITH Safeset® RESERVOIR AND BLOOD SAMPLING PORT, 24" (60 cm) TUBING, DISPOSABLE TRANSDUCER, 3 ML INTRAFLO® FLUSH, MACRODRIP (PATIENT MOUNT)	Class IIb, Rule 10	45275
011-42650-06	Transpac® TRIFURCATED MONITORING KIT WITH Safeset® RESERVOIR AND 2 BLOOD SAMPLING PORTS, 84" (213 cm), 3 3 ML SQUEEZE FLUSHES, 3 DISPOSABLE TRANSDUCERS, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42650-16	Transpac® TRIFURCATED MONITORING KIT WITH Safeset® RESERVOIR AND 2 BLOOD SAMPLING PORTS, 84" (213 cm) TUBING, 3 3 ML SQUEEZE FLUSHES, 3 DISPOSABLE TRANSDUCERS, MACRODRIP	Class IIb, Rule 10	45275
011-42652-05	Transpac® IV BIFURCATED MONITORING KIT 72 INCH (182 cm), 2 DISPOSABLE TRANSDUCERS, 2 3 ML SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-42653-66	Neonatal/Pediatric Safeset® Reservoir with Needleless Valve	Class IIa, Rule 2	45760
011-46073-11	Cardiac Catheterization Basic Kit With Transpac® IV Disposable Transducer And 3-Station, Right, ON, High Pressure Manifold (600 PSI/ 41 bar/ 4.1 MPa)	Class IIb, Rule 10	45275
011-46100-48	2 Bifurcated Cath Lab Kits w/2 2 Port "OFF" Manifolds (600 PSI/41 bar/ 4.1 MPa), IT Transpac®, 03 ml Squeeze Flush Devices	Class IIb, Rule 10	45275
011-46100-57	72" (182 cm) High Pressure Tubing w/Rotator	Class IIa, Rule 2	35529
011-46100-61	Venous Manifold 3 Port/Off/Right 3 Way (600 PSI/41 bar/ 4.1 MPa) w/Transpac® IV, 1 Way Stopcock, 48" (122 cm) Blue Stripe TBG and Manifold 1 Port/Off/3 Way/RA (600 PSI/41 bar/ 4.1 MPa)	Class IIb, Rule 10	45275
011-46100-62	Arterial Manifold 3 Port/Off/Right 3 Way (600 PSI/41 bar/ 4.1 MPa) w/Transpac® IV and 1 Way Stopcock	Class IIb, Rule 10	45275
011-46100-63	Cath Lab Kit w/Transpac® IV, 3 Station "OFF" Manifold Rotator, 4 Way Stopcocks and Admin Sets	Class IIb, Rule 10	45275
011-46100-64	48" (122 cm) Red Striped Extension Set w/High Pressure Stopcock (600 PSI/41 bar/ 4.1 MPa) 3 Way Rotator and Red Indicator	Class IIa, Rule 2	16545
011-46102-55	03 ml Safeset™ Reservoir Kit w/Single Needleless Valve	Class IIa, Rule 2	45760
011-46103-05	Safeset® Transpac® IT w/3 ml Reservoir and Single Needleless Valve, Without Velcro Arm Strap, Patient Mount.	Class IIb, Rule 10	45275
011-46103-06	TRANSDUCER, 72 INCH (182 CM), 3 ml/hr, MACRODRIP	Class IIb, Rule 10	45275
011-46103-07	Transpac® IT Bifurcated Monitoring Kit w/ Safeset® Reservoir and Blood port, Stopcock	Class IIb, Rule 10	45275
011-46103-08	ICP Transpac® IV Monitoring Kit with 2 Stopcock	Class IIb, Rule 10	35927
011-46103-09	Transpac® IV Monitoring Kit W/30 ml FLUSH DEVICE	Class IIb, Rule 10	45275
011-46103-11	Transpac® IV Monitoring Kit w/Safeset® 84" (213 cm) Arterial Pressure Tubing, Reservoir, Squeeze Flush and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46103-12	Bifurcated Monitoring Kit w/Safeset™ Reservoir and Transpac® IT	Class IIb, Rule 10	45275
011-46103-13	Trifurcated Monitoring Kit w/Safeset™ Reservoir and Transpac® IT	Class IIb, Rule 10	45275
011-46103-14	SAFETSET™, Transpac® IT, BLOOD SAMPLING PORT, 90 INCH (228.6 CM), 3ml/hr MACRODRIP	Class IIb, Rule 10	45275
011-46103-16	MONITORING KIT FOR NEONATAL/CHILDRENS	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46103-17	Transpac® Neonatal Custom Kit w/Red Stripe Tubing	Class IIb, Rule 10	45275
011-46103-21	1 LINE, 1 TRANSDUCER 24 INCH (61 CM) 3 ML/HR	Class IIb, Rule 10	45275
011-46103-22	Monitoring Kit w/TP4, 30 ml Squeeze Flush and Needleless Valve	Class IIb, Rule 10	45275
011-46103-23	Transpac® IV w/03 ml Intraflo Device, 3 Way Stopcock and 66" (167 cm) Pressure Tubing .	Class IIb, Rule 10	45275
011-46103-24	1 LINE, 1 TRANSDUCER 60" (152CM) RED STRIPE TUBING, 3 ML/HR MACRODRIP	Class IIb, Rule 10	45275
011-46103-25	Safeset® Transpac® IV w/ 3 ML RESERVOIR and SINGLE BLOOD SAMPLING PORT, PATIENT MOUNT	Class IIb, Rule 10	45275
011-46103-28	Transpac® IV MONITORING KIT WITH 2 3ML FLUSH DEVICES, MACRODRIP	Class IIb, Rule 10	45275
011-46103-29	Transpac® Trifurcated Monitoring Kit, 60" (152cm) Stripe Tubing, 3 3 ml Flush Device, Macrodrrip	Class IIb, Rule 10	45275
011-46103-30	Transpac® IV MONITORING KIT, 72" (182cm) RED STRIPE TUBING, 3 ML FLUSH DEVICE, MACRODRIP	Class IIb, Rule 10	45275
011-46103-31	1 LINE 1 TRANSDUCER, 9 INCH (23 CM), 3ML/HR, MACRODRIP, PATIENT MOUNT	Class IIb, Rule 10	45275
011-46103-33	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, TP4,86" (218 cm) Tubing, 4 Way Red Stopcock and Macrodrrip	Class IIb, Rule 10	45275
011-46103-34	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, TP4, 86" (218 cm) Tubing,4 Way Blue Stopcock and Macrodrrip	Class IIb, Rule 10	45275
011-46103-37	1 LINE, 1 TRANSDUCER 72 INCH (182 CM) BLUE STRIPE TUBING, 3 ML/HR MACRODRIP	Class IIb, Rule 10	45275
011-46103-38	Transpac® IV Monitoring Kit w/Safeset® Reservoir, 60" (152cm) Arterial Pressure Tubing, 03 ml Squeeze Flush and 1 Needleless Valve	Class IIb, Rule 10	45275
011-46103-40	Transpac®IT Monitoring Kit w/Safeset® Reservoir, 03 ml Flush Device, 48" (122 cm) Tubing and Macrodrrip	Class IIb, Rule 10	45275
011-46103-47	QUAD MONITORING KIT w/Transpac® IT	Class IIb, Rule 10	45275
011-46103-50	Transpac® IV MONITORING KIT, 72" (182cm), DISPOSABLE TRANSDUCER, 03 ml SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-51	Transpac® IV BIFURCATED MONITORING KIT 60" (152cm), 2 DISPOSABLE TRANSDUCERS, 2 03 ml SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-52	Transpac® IV TRIFURCATED MONITORING KIT WITH MALE/MALE BRIDGE, 60" (152cm) , 2 DISPOSABLE TRANSDUCERS, 3 03 ml SQUEEZE FLUSHES, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-53	Transpac® IV BIFURCATED MONITORING KIT WITH MALE/MALE BRIDGE, 60" (152cm) , 2 03 ml SQUEEZE FLUSHES, MACRODRIP, DISPOSABLE TRANSDUCER (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-55	Transpac® IV BIFURCATED MONITORING KIT WITH MALE/MALE BRIDGE, 60" (152cm) , 2 3 ML INTRAFLO FLUSHES, MACRODRIP, DISPOSABLE TRANSDUCER (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-56	Transpac® IV TRIFURCATED MONITORING KIT WITH MALE/MALE BRIDGE, 60" (152cm) , 2 DISPOSABLE TRANSDUCERS, 3 3 ml SQUEEZE FLUSHES, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-57	Transpac® IV BIRFURCATED MONITORING KIT 60 INCH (152 cm), 2 DISPOSABLE TRANSDUCERS, 2 3 ML FLUSH DEVICE, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-58	Transpac® IV MONITORING KIT, 72" (182cm), DISPOSABLE TRANSDUCER, 3 ML INTRAFLO® DEVICE, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-82	Transpac® IV w/60" (152cm) Macro Admin Set, 03 ml Squeeze Flush, 4 Way Stopcock and Pressure Tubing.	Class IIb, Rule 10	45275
011-46103-86	Bifurcated Monitoring Kit w/Transpac® IV and Stripe Tubing	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46103-87	Transpac® IV MONITORING KIT WITH Safeset® RESERVIOR AND 2 BLOOD SAMPLING PORTS, 84" (213 cm) TUBING, DISPOSABLE TRANSDUCER, 03 ml SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-88	Transpac® IV BIFURCATED MONITORING KIT w/MALE/MALE BRIDGE, 60" (152cm) PRESSURE TUBING, 58" (147 cm) IV TUBING, 2 03 ml SQUEEZE FLUSHES, MACRODRIP, DISPOSABLE TRANSDUCER (POLE MOUNT)	Class IIb, Rule 10	45275
011-46103-89	1 LINE, 1 TRANSDUCER 60" (152CM) 3 ML/HR MACRODRIP w/ RED STRIPE TUBING	Class IIb, Rule 10	45275
011-46103-90	Safeset® - Transpac®IT with/3 ml Reservoir and Needleless Valve, Red Stripe Tubing, with Velcro Arm Strap, Patient Mount.	Class IIb, Rule 10	45275
011-46103-91	Transpac® IT Neonatal Monitoring Kit w/Needleless Valve	Class IIb, Rule 10	45275
011-46103-92	Transpac® IT w/ Safeset® RESERVOIR and NEEDLELESS VALVE	Class IIb, Rule 10	45275
011-46103-93	Transpac® IT w/ Safeset® RESERVOIR, RED STRIPE TUBING and NEEDLELESS VALVE	Class IIb, Rule 10	45275
011-46103-94	Transpac® IV Monitoring Kit w/Safeset®84" (213 cm) Red Stripe Arterial Pressure Tubing, Reservoir, Intraflo® and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46103-95	Transpac® IV Bifurcated Kit w/Safeset® Reservoir, 03 ml Intraflo® and Needleless Valve	Class IIb, Rule 10	45275
011-46103-98	BIFURCATED TP IT w/NEONATAL Safeset® RESERVOIR, NEEDLELESS VALVE, RED and BLUE STRIPE TUBING	Class IIb, Rule 10	45275
011-46103-99	TRIFURCATED TP IT w/NEONATAL Safeset® RESERVOIR, NEEDLELESS VALVE, RED, YELLOW and BLUE STRIPE TUBING	Class IIb, Rule 10	45275
011-46104-01	Single TP IT w/ Neonatal Safeset® Reservoir, Needleless Valve and Red Stripe Tubing	Class IIb, Rule 10	45275
011-46104-02	1 LINE, 1 TRANSDUCER 60" (152CM) 3 ML/HR MACRODRIP	Class IIb, Rule 10	45275
011-46104-03	1 LINE 1 TRANSDUCER, 9 INCH (23 CM), 3ML/HR, MACRODRIP, PATIENT MOUNT	Class IIb, Rule 10	45275
011-46104-12	Neonatal Safeset® Reservoir w/30 ml Squeeze Flush, Needleless Valve and TP4	Class IIb, Rule 10	45275
011-46104-18	Transpac® IT w/Single Needleless Valve and Velcro Arm Strap, Patient Mount	Class IIb, Rule 10	45275
011-46104-19	NEONATAL Safeset® Transpac® IT w/3ml RESERVIOR and SINGLE NEEDLELESS VALVE AND VELCRO ARM STRAP, PATIENT MOUNT	Class IIb, Rule 10	45275
011-46104-20	TP IT Monitoring Kit w/Safeset® Reservoir and Red Stripe Tubing	Class IIb, Rule 10	45275
011-46104-21	Bifurcated TP IT w/Safeset® Reservoir, Red and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46104-33	Trifurcated Transpac® IT Monitoring Kit w/03 ml Flush Devices, Needleless Valve and Macrodrrip	Class IIb, Rule 10	45275
011-46104-34	Bifurcated Transpac® IT Monitoring Kit w/03 ml Flush Device, Needleless Valve, Macrodrrip	Class IIb, Rule 10	45275
011-46104-36	Transpac® IV MONITORING KIT 72 INCH (182 cm), DISPOSABLE TRANSDUCER, 3 ML INTRAFLO® FLUSH AND MACRODRIP	Class IIb, Rule 10	45275
011-46104-37	Quad Monitoring Kit w/Transpac® IV, 03 ml Squeeze Flush, PT Tubing and Needleless valves	Class IIb, Rule 10	45275
011-46104-39	Transpac® IV w/Safeset® RESERVOIR and NEEDLELESS VALVE	Class IIb, Rule 10	45275
011-46104-40	Quad Transpac® IV Monitoring Kit w/ 66" (167 cm) Safeset® Reservoir, Red and Blue Stripe Tubing and 03 ml Intraflo Device.	Class IIb, Rule 10	45275
011-46104-41	Transpac® IV Monitoring Kit, 84" (213 cm), Disposable Transducer, 3 ml Squeeze Flush, Macrodrrip	Class IIb, Rule 10	45275
011-46104-42	Safeset® Transpac® IT w/3 ml Reservoir and Single Needleless Valve, With Velcro Arm Strap, Patient Mount	Class IIb, Rule 10	45275
011-46104-49	Transpac® IV w/ Safeset® RESERVOIR, 03 ml SQUEEZE FLUSH and 2 NEEDLELESS VALVES	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46104-50	Transpac® IV Dual Bifurcated/Trifurcated Monitoring Kit w/2 Disposable Transducer, 03 ml Squeeze Flush, Safeset® Reservoir and 3 Needleless Valve	Class IIb, Rule 10	45275
011-46104-51	Transpac® IV Add On Kit w/03ml Squeeze Flush, 60" (152cm) Yellow Stripe PT Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46104-52	Single Line Monitoring Kit w/Transpac® IV, 03 ml Squeeze Flush, Needleless Valve and 58" (147 cm) Blue Stripe PT Tubing	Class IIb, Rule 10	45275
011-46104-58	Transpac® IV MONITORING KIT, 72" (182cm), DISPOSABLE TRANSDUCER, 3 ML SQUEEZE FLUSH, MACRODRIP (POLE MOUNT)	Class IIb, Rule 10	45275
011-46104-59	Single Monitoring Kit w/Transpac® IV and 03 ml Flush Device	Class IIb, Rule 10	45275
011-46104-60	Bifurcated Monitoring Kit w/Transpac® IV and 03 ml Flush Device	Class IIb, Rule 10	45275
011-46104-61	Single Monitoring Kit w/Transpac® IV, 03 ml Intraflo® Flush Device and PT Tubing	Class IIb, Rule 10	45275
011-46104-62	Neonatal Safeset® Transpac® IT Monitoring Kit w/03 ml Safeset® Reservoir and Needleless Valve, with Velcro Arm Strap, Patient Mount	Class IIb, Rule 10	45275
011-46104-67	Transpac® IT Monitoring Kit, 72" (182cm) Tubing, 03 ml Flush Device, Needleless Valve	Class IIb, Rule 10	45275
011-46104-68	Transpac® IV Monitoring Kit w/Safeset® Reservoir, 03 ml Squeeze Flush Device and Red, Blue Stripe PT Tubing	Class IIb, Rule 10	45275
011-46104-69	ICP Single MONITORING Line, Transpac® IV, 12" (30 cm) Green Stripe Tubing, Macrodrrip and NO FLUSH	Class IIb, Rule 10	35927
011-46104-70	Bifurcated Transpac® IT Monitoring Kit w/03 ml Flush Device, Red and Blue Stripe Tubing, Needleless Valve, Macrodrrip	Class IIb, Rule 10	45275
011-46104-71	Trifurcated Transpac® IT Monitoring Kit w/03 ml FLush Devices, Stripe Tubing, Needleless Valve and Macrodrrip	Class IIb, Rule 10	45275
011-46104-77	Transpac® IV Monitoring Kit w/Safeset® Reservoir, 84" (213 cm), Red Stripe Arterial Pressure Tubing, 03 ml Intraflo® and 2 Safeset® Blood Ports	Class IIb, Rule 10	45275
011-46104-78	Transpac® IV Bifurcated Kit w/Safeset® Reservoir, 03 ml Intraflo® and Safeset® Blood Ports	Class IIb, Rule 10	45275
011-46104-81	Bifurcated Monitoring Kit w/ Transpac® IV, Stripe Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46104-83	Transpac® IT Neonatal Monitoring Kit w/30 ml Flush Device, Safeset® Reservoir and Blood Sampling Port	Class IIb, Rule 10	45275
011-46104-86	Double Line Kit w/ Transpac® IT 03 ml, 60" (152cm) Admin Set, 4 Way Stopcock	Class IIb, Rule 10	45275
011-46104-89	Bifurcated Transpac® IV Monitoring Kit w/ 03 ml Intraflo® Flush Device, Macrodrrip® and 3 Way Stopcock	Class IIb, Rule 10	45275
011-46104-90	Quad Transpac® IV Monitoring Kit w/03 ml Intraflo® Flush Device, 72" (182cm) Red and Blue Stripe PT Tubings	Class IIb, Rule 10	45275
011-46104-93	Transpac® IV w/30 ml Squeeze Flush and Needleless Valves	Class IIb, Rule 10	45275
011-46105-07	Custom Kit w/3 Way Stopcock, Pressure Tubing, 10 ml Touch Contamination Sheath and Needleless Valve	Class IIa, Rule 2	35529
011-46105-08	ADD ON Safeset® RESERVOIR and 2 NEEDLELESS VALVE	Class IIa, Rule 2	45760
011-46105-30	1 Way Stopcock, 8" (20 cm) Pressure Tubing and Male Luer Lock	Class IIa, Rule 2	35529
011-46105-32	Safeset® Reservoir	Class IIa, Rule 2	45760
011-46105-33	Male/Female Dead End Cap	Class IIa, Rule 2	60538
011-46105-35	Arterial Blue Stripe Pressure Tubing, 60 Inches (150 cm) w/3 Way Stopcock	Class IIa, Rule 2	32172
011-46105-42	Safeset® Reservoir w/Red Male/Female Connectors	Class IIa, Rule 2	45760
011-46105-45	10" (25cm) Arterial Pressure Tubing Set w/Needleless Valve	Class IIa, Rule 2	35529
011-46105-46	Arterial Blue Stripe Pressure Tubing, 60 Inches (150 cm) w/3 Way Stopcock	Class IIa, Rule 2	32172
011-46105-48	44" (111 cm) Bifurcated Administration Set	Class IIa, Rule 2	58977

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46105-50	Add On Arterial Kit w/03 ml Safeset® Reservoir and Needleless Valve	Class IIa, Rule 2	45760
011-46105-52	60" (152cm) Administration Set Macro drip	Class IIa, Rule 2	58977
011-46105-53	Bifurcated Administration Set Macro drip	Class IIa, Rule 2	58977
011-46105-54	Trifurcated Administration Set Macro drip	Class IIa, Rule 2	58977
011-46105-57	6" (15 cm) Red Stripe Tubing w/Needleless Valve	Class IIa, Rule 2	35529
011-46105-58	Lap Green Stripe Pressure Tubing 60" (152cm)	Class IIa, Rule 2	35529
011-46105-59	PA Pressure Tubing 60" (152cm)	Class IIa, Rule 2	35529
011-46105-61	Add On Kit w/03 ml Safeset® Reservoir and 2"/5 cm (Red Stripe Pressure Tubing	Class IIa, Rule 2	45760
011-46105-66	Add On Kit w/10 ml Safeset® Reservoir, Needleless Valve and Clear PT Tubing	Class IIa, Rule 2	45760
011-46105-68	84" (213 cm) Arterial Pressure Tubing	Class IIa, Rule 2	35529
011-46105-69	Extension Set 35 cm Red Stripe Tubing w/3 Way Stopcock and Male Luer	Class IIa, Rule 2	35529
011-46105-70	Extension Set 110 cm Red Stripe Tubing w/3 Way Stopcock and Male Luer Lock	Class IIa, Rule 2	35529
011-46105-74	Monitoring Kit w/225 cm Pressure Tubing and 2 4 Way Stopcocks	Class IIa, Rule 2	35529
011-46105-75	Monitoring Kit w/195 cm Yellow Stripe Tubing and 2 4 way stopcock	Class IIa, Rule 2	35529
011-46105-76	Blue Stripe Pressure Tubing 150 cm Male Male	Class IIa, Rule 2	35529
011-46105-77	Add On Kit w/03 ml Safeset® Reservoir and 2"/5 cm Red Stripe PT Tubing	Class IIa, Rule 2	45760
011-46105-78	Pressure Tubing 200 cm Male/Female and 2 Removable Clamps	Class IIa, Rule 2	35529
011-46105-79	Pressure Tubing 150 cm Male/Female and 2 Removable Clamps	Class IIa, Rule 2	35529
011-46105-83	96" (243 cm) Arterial Pressure Tubing Male/Male	Class IIa, Rule 2	35529
011-46105-85	24" (60 cm) Arterial Red Stripe Pressure Tubing w/Red Connectors	Class IIa, Rule 2	35529
011-46105-86	60" (152cm) Arterial Red Stripe Pressure Tubing w/Red Connectors	Class IIa, Rule 2	35529
011-46105-97	Venous 10 ml Safeset® Reservoir w/CSP, Neutron, Bracket and Arm Strap	Class IIa, Rule 2	45760
011-46106-12	Trifurcated Transpac™ IT Monitoring Kit w/03 ml Flush Device, Adaptor Rotating Male/Female and Macro drip™	Class IIb, Rule 10	45275
011-46106-13	Bifurcated Transpac® IT Monitoring Kit w/03 ml Flush Device, Adaptor Rotating Male/Female and Macro drip®	Class IIb, Rule 10	45275
011-46106-20	Transpac® IV Kit w/03 ml Squeeze Flush Device, 10ml Safeset® Reservoir, Needleless Valve and Admin Set	Class IIb, Rule 10	45275
011-46106-22	Trifurcated Transpac® IV Monitoring Kit w/Safeset™ Reservoir, 03 ml Squeeze Flush and 6 Needleless Valves	Class IIb, Rule 10	45275
011-46106-23	Transpac® IT Monitoring Kit w/Safeset™ Reservoir, 03 ml Flush Device, 84" (213 cm) Red Stripe Pressure Tubing and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46106-28	Transpac® IV Neonatal Monitoring Kit w/30 ml Squeeze Flush Device, 03 ml Safeset® Reservoir and Port	Class IIb, Rule 10	45275
011-46106-29	Single Transpac® IT Monitoring Kit w/03 ml Flush Device, Needleless Valve, Macro drip®	Class IIb, Rule 10	45275
011-46106-31	60" (152cm) Macro drip Chamber w/ Transpac® IV and 3 ml Squeeze Flush Device	Class IIb, Rule 10	45275
011-46106-32	Transpac® IT Monitoring Kit w/ Blue and Red Stripe Pressure Tubing , 60 INCH (152 CM), 3 ml/hr, Macro drip	Class IIb, Rule 10	45275
011-46106-36	Transpac® IT Monitoring Kit w/03 Flush Device and Safeset™ Reservoir	Class IIb, Rule 10	45275
011-46106-39	Transpac® IT Monitoring Kit w/03 ml Flush Device, Safeset® Reservoir and Needleless Valve	Class IIb, Rule 10	45275
011-46106-45	Transpac® IV MONITORING KIT, DISPOSABLE TRANSDUCER, 3 ML SQUEEZE FLUSH, MACRODRIP	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46106-50	Transpac® IT Monitoring Kit w/Blue and Red Stripe Pressure Tubing, 108 Inch (270 cm), 03 ml/hr Flush Device	Class IIb, Rule 10	45275
011-46106-51	Transpac® IV Monitoring Kit w/60" (152 cm) of Yellow Stripe Tubing	Class IIb, Rule 10	45275
011-46106-61	Bifurcated Transpac® IV Monitoring Kit w/ 03 ml Squeeze Flush and 64" (160cm) Blue and Red Stripe Tubing	Class IIb, Rule 10	45275
011-46106-63	Bifurcated Transpac® IV Monitoring Kit w/ 03 ml Squeeze Flush and 60" (152cm) Blue and Red Stripe Tubing	Class IIb, Rule 10	45275
011-46106-64	Bifurcated Transpac® IV Monitoring Kit w/ 03 ml Squeeze Flush and 83" (210cm) Blue and Red Stripe Tubing	Class IIb, Rule 10	45275
011-46106-71	Transpac® IV Monitoring Kit w/Safeset™ Reservoir, 03 ml Squeeze Flush and Needleless Valve	Class IIb, Rule 10	45275
011-46106-72	Transpac® IT Monitoring Kit w/Safeset® Reservoir, 03 ml Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46106-73	Transpac® IT w/03 ml Flush Device, Admin Set, Blue, Yellow Striped Pressure Tubing and 3 Way Stopcock	Class IIb, Rule 10	45275
011-46106-74	Transpac® IV w/03 ml Squeeze Flush Device, 60" (152cm) Macro Admin Set and Pressure Tubing (152CM)	Class IIb, Rule 10	45275
011-46106-75	Bifurcated Transpac® IV w/ 03 ml Squeeze Flush Device, Admin Set, Red and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46106-76	Transpac® IT w/ 03 ml Flush and Red Stripe Tubing	Class IIb, Rule 10	45275
011-46106-77	Transpac® IV Monitoring Kit w/Safeset®84" (213 cm) Arterial Pressure Tubing, Reservoir, Squeeze Flush and Needleless Valve	Class IIb, Rule 10	45275
011-46106-78	Bifurcated Transpac® IT w/Safeset®72" (182cm) Reservoir, Pressure Tubing and Cannulas	Class IIb, Rule 10	45275
011-46106-84	Transpac® IT Bifurcated Monitoring Kit w/2 03 ml Flush Devices and Macrodrrip	Class IIb, Rule 10	45275
011-46106-93	Transpac® IT Monitoring Kit w/03 ml Flush Device, 03 ml Safeset® Reservoir, Needleless Valve and Velcro Arm Strap	Class IIb, Rule 10	45275
011-46106-95	Transpac® IT w/3 ml/hr, Needleless Valve, Macrodrrip and Patient Mount	Class IIb, Rule 10	45275
011-46106-96	Transpac® IT w/3 ML/HR Macrodrrip, Arterial Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46106-97	Transpac® IV w/03 ml Squeeze Flush, 3 Way Stopcock and Adaptor Rotating Male/Female	Class IIb, Rule 10	45275
011-46106-98	Transpac® IV 60" (152CM) 3 ML/HR Macrodrrip and Needleless Valve	Class IIb, Rule 10	45275
011-46106-99	Transpac® IT 60" (152cm) (152CM) 3 ML/HR Macrodrrip and Needleless Valve	Class IIb, Rule 10	45275
011-46107-01	ICP Kit w/Transpac® IV, Stopcocks and 60" (152 cm) PT Tubing	Class IIb, Rule 10	35927
011-46107-02	ICP Kit w/Transpac® IV, Stopcocks and 60" (152 cm) PT Tubing	Class IIb, Rule 10	35927
011-46107-03	Transpac® IV Trifurcated Monitoring Kit w/03 ml Squeeze Flush, 72" (182cm) Pressure Tubing and Administration Set	Class IIb, Rule 10	45275
011-46107-04	Transpac® IV w/03 ml Squeeze Flush and Administration Set	Class IIb, Rule 10	45275
011-46107-05	Transpac® IV Bifurcated Monitoring Kit w/03 ml Squeeze Flush, 3 Way Stopcocks, 60" (152cm) Pressure Tubing and Administration Set	Class IIb, Rule 10	45275
011-46107-06	Transpac® IV Trifurcated Monitoring Kit w/03 ml Squeeze Flush, 3 Way Stopcocks, 60" (152cm) Pressure Tubing and Administration Set	Class IIb, Rule 10	45275
011-46107-07	Transpac® IV Bifurcated Monitoring Kit w/03 ml Squeeze Flush, 72" (182cm) Pressure Tubing and Administration Set	Class IIb, Rule 10	45275
011-46107-09	Transpac® IV w/30 ml Squeeze Flush, Safeset® Sampling Port and 48" (122 cm) Neonatal Reservoir (121 cm)	Class IIb, Rule 10	45275
011-46107-10	Transpac® IT w/30 ML/HR, Safeset® Sampling Port and 48" (122 cm) Neonatal Reservoir (121 cm)	Class IIb, Rule 10	45275
011-46107-11	Transpac® IT Monitoring Kit w/03 ml Safeset®Reservoir and Needleless Valve, with Velcro Arm Strap, Patient Mount	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46107-12	Arterial Transpac® IT Monitoring Kit w/Safeset® Reservoir, 03 ml Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46107-13	ICP Kit Single Monitoring Line w/Transpac® IV, Macrodrip and No Flush Device	Class IIb, Rule 10	35927
011-46107-14	Transpac® IT Trifurcated Monitoring Kit w/3 03 ml Flush Devices Safeset® Reservoir and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46107-15	Bifurcated Transpac® IV Monitoring w/03 ml Squeeze Flush, 60" (152cm) Pressure Tubing and Needleless Valves	Class IIb, Rule 10	45275
011-46107-16	Single Line Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Safeset® Reservoir and 3 Needleless Valves	Class IIb, Rule 10	45275
011-46107-17	Bifurcated Transpac® IV Monitoring Kit w/Safeset® Reservoir, 03 ml Squeeze Flush and 5 Needleless Valves	Class IIb, Rule 10	45275
011-46107-18	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, 72" (182cm) PT Tubing and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46107-25	CVP and Arterial Transpac® IT Bifurcated Monitoring Kit w/Safeset™ Reservoir, Needleless Valves and 03 ml Flush Devices	Class IIb, Rule 10	45275
011-46107-27	Trifurcated Monitoring Kit w/Transpac™, 3ml Squeeze Flush, Safeset™ Reservoir and Needleless Valve	Class IIb, Rule 10	45275
011-46107-28	Bifurcated Monitoring Kit w/Transpac® IV, 03 ml Squeeze Flush and Safeset™ Reservoir w/Needleless Valve	Class IIb, Rule 10	45275
011-46107-29	Quad Line Transpac® IV Monitoring Kit w/03 ml Squeeze Flush and Safeset™ Reservoir w/Needleless Valve	Class IIb, Rule 10	45275
011-46107-30	Single Line Transpac® IV Monitoring Kit w/03 ml Squeeze Flush and 60" Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46107-31	Transpac® IV Monitoring Kit w/Safeset™ Reservoir, 03 ml Squeeze Flush Device and Needleless Valve	Class IIb, Rule 10	45275
011-46107-33	Transpac® IT Bifurcated Kit w/03 ml Flush Device, Proximal/PA Monitoring Kit	Class IIb, Rule 10	45275
011-46107-34	Single PA Line Transpac® IT Monitoring Kit w/03 ml Flush Device and Macrodrip	Class IIb, Rule 10	45275
011-46107-40	Arterial Transpac® IT Monitoring Kit, 03 ml Flush Device, 92" (233 cm) and Needleless Valve	Class IIb, Rule 10	45275
011-46107-41	Transpac® IT Trifurcated Monitoring Kit w/3 03 ml Flush Device and Needleless Valve	Class IIb, Rule 10	45275
011-46107-42	Transpac® IT Trifurcated Monitoring Kit w/Safeset® Reservoir, 3 03 ml Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46107-43	Transpac® IT Monitoring Kit w/03 ml Flush Device, Safeset® 60" (152 cm) Reservoir and Needleless Valves	Class IIb, Rule 10	45275
011-46107-44	Transpac® IT Monitoring Kit w/03 ml Flush Device, Safeset® 78" (198 cm) Reservoir and Needleless Valves	Class IIb, Rule 10	45275
011-46107-45	Trifurcated Transpac® IT w/Safeset® Reservoir, Needleless Valves, Red, Yellow and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46107-46	Transpac® IT Monitoring Kit w/30 ml Flush Device, 1 Way Stopcock and Pressure Tubing	Class IIb, Rule 10	45275
011-46107-47	Transpac® IT Monitoring Kit w/ 03 ml Flush Device, Safeset® Reservoir and Admin Set	Class IIb, Rule 10	45275
011-46107-48	Trifurcated Transpac® IT w/ 03 ml Flush, Safeset® Reservoir, Sample Ports, Red, Yellow and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46107-49	Bifurcated Transpac® IT w/ 03 ml Flush, Safeset® Reservoir, Sample Ports, Red and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46107-50	Bifurcated Transpac® IT, 03 ml Flush Device, Admin Set, Red and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46107-55	Transpac® IV Monitoring Kit w/03 ML Squeeze Flush, Safeset® Reservoir, 84" (213 cm) Arterial Pressure Tubing, and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46107-65	Transpac® IT Monitoring Kit w/03 ml Flush Device, Needleless Valve and 7" (17 cm) Red Stripe PT Tubing	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46107-66	Transpac® IT Monitoring Kit w/03 ml Flush Device, Needleless Valve and 9" (22 cm) Blue Stripe PT Tubing	Class IIb, Rule 10	45275
011-46107-71	Transpac® IV Custom Kit Macro drip In-Line w/03 ml Squeeze Flush Device, 3 Way Stopcock and IV Tubing	Class IIb, Rule 10	45275
011-46107-72	Transpac® IV Custom Kit Macro drip In-Line w/03 ml Squeeze Flush Device, 3 Way Stopcocks, Pressure Tubing, IV Tubing	Class IIb, Rule 10	45275
011-46107-84	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Needleless Valve and Patient Mount	Class IIb, Rule 10	45275
011-46107-85	Transpac® IV Monitoring w/03 ml Squeeze Flush, Arterial Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46107-86	Arterial Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, 92" (233 cm) and Needleless Valve	Class IIb, Rule 10	45275
011-46107-87	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, 92" (233 cm) Red Stripe PT Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46107-88	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, 60" (152cm) Red Stripe Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46107-89	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Needleless Valve and Patient Mount	Class IIb, Rule 10	45275
011-46107-90	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, 60" (152cm) PT Tubing, Needleless Valve and Pole Mount	Class IIb, Rule 10	45275
011-46107-91	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, 72" (182cm) PT Tubing and Pole Mount	Class IIb, Rule 10	45275
011-46107-92	Bifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush and PT Tubings	Class IIb, Rule 10	45275
011-46107-93	Bifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Red and Blue Stripe PT Tubings	Class IIb, Rule 10	45275
011-46107-94	Bifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Needleless Valve, Red and Blue Stripe PT Tubing	Class IIb, Rule 10	45275
011-46107-95	Bifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Needleless Valve and PT Tubing	Class IIb, Rule 10	45275
011-46107-96	Trifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush and PT Tubing	Class IIb, Rule 10	45275
011-46107-97	Trifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Red, Blue and Yellow PT Tubing	Class IIb, Rule 10	45275
011-46107-98	Trifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Needleless Valve, Red, Blue and Yellow PT Tubing	Class IIb, Rule 10	45275
011-46107-99	Trifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Safeset® Reservoir, 2 Needleless Valves and PT Tubing	Class IIb, Rule 10	45275
011-46108-01	ICP Transpac® IV Monitoring Kit w/03 ml Squeeze Flush and 72" (182cm) PT Tubing	Class IIb, Rule 10	35927
011-46108-02	Transpac® IT Trifurcated Monitoring Kit w/Safeset® Reservoir, 60" (152cm) Tubing, 3 03 ml Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-03	Transpac® IT Bifurcated Monitoring Kit w/Safeset® Reservoir, 60" (152cm) Tubing, 2 03 ml Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-04	1 Line, 1 Transducer 60" (152CM) 03 ML/HR Macro drip and Needleless Valve	Class IIb, Rule 10	45275
011-46108-05	Transpac® IT Monitoring Kit w/03 ml Flush Device, Safeset® Reservoir and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-06	Transpac® IT Bifurcated Monitoring Kit w/Safeset® Reservoir, 60" (152cm) Tubing, 2 03 ml Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-07	CVP and Arterial Transpac® IV Bifurcated Monitoring Kit w/Safeset® Reservoir and 03 ml Flush Devices	Class IIb, Rule 10	45275
011-46108-08	Bifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Safeset® Reservoir, 2 Needleless Valves and Stripe PT Tubings	Class IIb, Rule 10	45275
011-46108-09	CVP and Arterial Transpac® IT Bifurcated Monitoring Kit w/Safeset® Reservoir and 03 ml Flush Devices	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46108-10	Bifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Safeset® Reservoir, 2 Needleless Valves and PT Tubings	Class IIb, Rule 10	45275
011-46108-11	CVP and Arterial Transpac® IV Bifurcated Monitoring Kit w/Safeset® Reservoir and 03 ml Flush Devices	Class IIb, Rule 10	45275
011-46108-12	Transpac® IV Trifurcated Monitoring Kit w/3 03 ml Flush Devices Safeset® Reservoir and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-13	Transpac® IT Trifurcated Monitoring Kit w/3 03 ml Flush Devices Safeset® Reservoir and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-14	Transpac® IV Trifurcated Monitoring Kit w/3 03 ml Flush Devices Safeset® Reservoir and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-15	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush and 72" (182cm) Blue Stripe PT Tubing	Class IIb, Rule 10	45275
011-46108-16	Transpac® IV With 4 Way Stopcocks and Disposable Transducer	Class IIb, Rule 10	45275
011-46108-17	Transpac® IT Trifurcated Monitoring Kit w/3 03 ml Flush Device and Needleless Valve	Class IIb, Rule 10	45275
011-46108-18	Trifurcated Transpac® IT Monitoring Kit w/03 ml Flush Devices, PT Tubings and Needleless Valve	Class IIb, Rule 10	45275
011-46108-19	Trifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Needleless Valve and PT Tubings	Class IIb, Rule 10	45275
011-46108-20	Trifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Safeset® Reservoir, 2 Needleless Valves and PT Tubing	Class IIb, Rule 10	45275
011-46108-21	Transpac® IT Trifurcated Monitoring Kit w/Safeset® Reservoir, 60" (152cm) Tubing, 3 03 ml Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-22	Transpac® IV Monitoring Kit w/03 ml Flush Device, 03 ml Safeset® Reservoir, Needleless Valve and Velcro Arm Strap	Class IIb, Rule 10	45275
011-46108-23	Transpac® IT Monitoring Kit w/03 ml Flush Device and Safeset® Reservoir and Blood Sampling Port	Class IIb, Rule 10	45275
011-46108-24	Trifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Needleless Valve and PT Tubings	Class IIb, Rule 10	45275
011-46108-25	Transpac® IV Trifurcated Monitoring Kit w/3 03 ml Squeeze Flush Devices Safeset® Reservoir and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-26	Transpac® IT Monitoring Kit w/30 ml Flush Device	Class IIb, Rule 10	45275
011-46108-27	Arterial Transpac® IV Monitoring Kit w/Safeset® Reservoir and 03 ml Squeeze Flush Device and Needleless Valves	Class IIb, Rule 10	45275
011-46108-28	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, 9" (23 cm) Red Stripe TBG and Patient Mount	Class IIb, Rule 10	45275
011-46108-29	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, Safeset® Arterial Pressure Tubing, Reservoir, Bag Spike and Needleless Valve	Class IIb, Rule 10	45275
011-46108-30	Transpac® IT Monitoring Kit w/03 Flush Device, 9" (23 cm) Arterial TBG and Patient Mount	Class IIb, Rule 10	45275
011-46108-31	Transpac® IT Trifurcated Monitoring Kit w/Safeset® Reservoir, 3 03 ml Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-32	Transpac® IV Monitoring Kit w/ 60" (152 cm) Arterial Pressure Tubing, 03 ml Intraflo Flush Device and Admin Set	Class IIb, Rule 10	45275
011-46108-33	Bifurcated Monitoring Kit w/03 ml Intraflo Flush Device, Transpac® IV, Safeset® Reservoir, Needleless Valve, Red and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46108-34	Bifurcated Monitoring Kit w/03 ml Intraflo Flush Device, Transpac® IV, 60' (150 cm) Red and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46108-35	Trifurcated Monitoring Kit w/03 ml Intraflo Flush Device, Transpac® IV, 60" (152 cm) Red, Blue and Yellow Stripe Tubing	Class IIb, Rule 10	45275
011-46108-37	Single Line Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, Needleless Valve and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46108-38	Single Line Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, Needleless Valve and Red Stripe Tubing	Class IIb, Rule 10	45275
011-46108-39	CVP Transpac® IT Monitoring Kit w/03 ml Flush Device, 60" (152cm) Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46108-40	Bifurcated Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device and 40 cm PT Tubings	Class IIb, Rule 10	45275
011-46108-41	Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device and 175 cm Red Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46108-42	Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device and 150 cm Blue Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46108-43	Transpac® IV w/30 ml Intraflo Flush Device, 40" (100 cm) Red Stripe PT Tubing and 4 Way Stopcock	Class IIb, Rule 10	45275
011-46108-44	Transpac® IV w/30 ml Intraflo Flush Device, 64" (160 cm) PT Tubing and 4 Way Stopcock	Class IIb, Rule 10	45275
011-46108-45	Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device, 200 cm Red Stripe Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46108-46	Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device, 165 cm Yellow Stripe Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46108-47	Transpac® IV w/03 ml Intraflo Flush Device and 3 Way Stopcock	Class IIb, Rule 10	45275
011-46108-48	Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device, 10 ml Reservoir, 130 cm Red Stripe Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46108-49	Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device, 10 ml Reservoir, 180 cm Red Stripe Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46108-50	Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device, 10 ml Reservoir, 130 cm Red, Blue Stripe Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46108-51	Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device, 10 ml Reservoir, Red, Blue Stripe Pressure Tubing and 2 Needleless Valve	Class IIb, Rule 10	45275
011-46108-52	4 Line Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device, 10 ml Reservoir, Red, Blue Stripe Pressure Tubing and 2 Needleless Valve	Class IIb, Rule 10	45275
011-46108-53	Bifurcated Transpac® IV Monitoring Kit w/03 ml Intraflo Flush Device, 10 ml Safeset® Reservoir, Red, Blue Stripe Pressure Tubing and Needleless Valves	Class IIb, Rule 10	45275
011-46108-54	Transpac® IT, w/30 ml Flush Device, 63" (160 cm) Safeset® Reservoir, Red Stripe Tubing and 3 Way Stopcocks	Class IIb, Rule 10	45275
011-46108-55	Transpac® IT, w/30 ml Flush Device, 63" (160 cm) Blue Stripe Tubing and 3 Way Stopcocks	Class IIb, Rule 10	45275
011-46108-60	Transpac® IV w/03 ml Squeeze Flush Device, 84" (213 cm) Pressure Tubing and Macro Admin Set 60" (152 cm)	Class IIb, Rule 10	45275
011-46108-61	Transpac® IV w/03 ml Squeeze Flush Device, 210 cm Pressure Tubing and Macro drip Chamber	Class IIb, Rule 10	45275
011-46108-63	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, 60" (152 cm) Red Stripe Pressure Tubing and 3 Way Stopcocks	Class IIb, Rule 10	45275
011-46108-64	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, 54" (135 cm) Blue Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46108-65	Bifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, 60" (152 cm) Red and Blue Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46108-66	Trifurcated Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, 60" (152 cm) Red, Blue and Yellow Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46108-67	Transpac® IV Monitoring Kit, 84" (213 cm) Red Stripe PT Tubing, Disposable Transducer and 03 ml Squeeze Flush	Class IIb, Rule 10	45275
011-46108-68	Transpac® IV Trifurcated Monitoring Kit w/3 03 ml Squeeze Flush Device, Red, Blue, and Yellow Stripe PT Tubings and Macro drip (Pole Mount)	Class IIb, Rule 10	45275
011-46108-69	Arterial Transpac® IT Monitoring Kit w/10 ml Safeset® Reservoir, 03 ml Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-70	CVP Transpac® IT Monitoring Kit, 72" (182 cm) Blue Stripe TBG and 03 ml Flush Device	Class IIb, Rule 10	45275
011-46108-71	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush, Safeset® Reservoir, 84" (213 cm) Clear Pressure Tubing, and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46108-97	Transpac® IT Monitoring Kit w/03 Flush Device, 12" (30 cm) Arterial TBG and Patient Mount	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46109-65	Transpac® IV Kit w/03 ml Squeeze Flush Device, 3 Way Stopcock, Admin Set, Red and Blue Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46109-73	Transpac® IV Neonatal Safeset® Reservoir w/30 ml Squeeze Flush Device and Needleless Valve	Class IIb, Rule 10	45275
011-46109-76	Transpac® IV Monitoring Kit w/30 ml Squeeze Flush Device, 03 ml Safeset® Reservoir and Port	Class IIb, Rule 10	45275
011-46109-77	Transpac® IT Monitoring Kit w/Safeset® Reservoir, 84" (213 cm) Arterial Pressure Tubing, 03 ml Flush Device, Needleless Valves and Red Indicator Plugs	Class IIb, Rule 10	45275
011-46109-78	Transpac® IT Bifurcated Kit w/Safeset® Reservoir, 03 ml Flush Device, Needleless Valves, Red and Blue Indicator Plugs	Class IIb, Rule 10	45275
011-46109-79	Transpac® IT Trifurcated Monitoring Kit w/84" (213 cm) Safeset® Reservoir, 03 ml Flush Device, Needleless Valves and Red, Blue and Yellow Indicator Plugs	Class IIb, Rule 10	45275
011-46109-90	Transpac® IT Bifurcated Monitoring Kit w/03 ml Flush Device, Safeset® Reservoir, 2 Sampling Ports and 6 Blunt Cannulas	Class IIb, Rule 10	45275
011-46109-91	Transpac® IT Bifurcated Monitoring Kit w/03 ml Flush Device, Safeset® Reservoir and 2 Sampling Ports	Class IIb, Rule 10	45275
011-46109-92	Transpac® IT Bifurcated Kit w/03 ml Flush Device, Safeset® Reservoir, 163 cm Red Stripe, Blue Stripe Pressure Tubing and Needleless Valves	Class IIb, Rule 10	45275
011-46109-93	Transpac® IV Monitoring Kit With Safeset® Reservoir and Blood Sampling Port, 182 cm Tubing, Disposable Transducer, 03 ml Squeeze Flush, Macro drip (Pole Mount)	Class IIb, Rule 10	45275
011-46109-96	Transpac® IT Monitoring Kit w/Safeset® Reservoir, 03 ml Flush Device, 163 cm Red Stripe Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46109-97	Single Line Transpac IV Monitoring Kit w/03 Squeeze Flush Device, CSP and Red Stripe Tubing	Class IIb, Rule 10	45275
011-46109-98	3 Line, 3 Transpac® IT, 60" (152 cm), 03 ml/hr Flush Device, Macro drip	Class IIb, Rule 10	45275
011-46110-06	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, Macro drip (Intended For Patient Mount)	Class IIb, Rule 10	45275
011-46110-08	Transpac® IT Monitoring Kit w/03 ml Flush Device, Safeset® Reservoir and 2 Sampling Ports	Class IIb, Rule 10	45275
011-46110-09	Transpac® IT 03 ml Safeset® Reservoir w/Needleless Valve and 30 ml Flush Device	Class IIb, Rule 10	45275
011-46110-10	Transpac® IV w/03 ml Squeeze Flush Device, 69" (175 cm) Pressure Tubing and Macro Admin Set 60" (152 cm)	Class IIb, Rule 10	45275
011-46110-13	Transpac® IV Monitoring Kit Disposable Transducer, 03 ml Squeeze Flush Device, In- Line Drip Chamber (INTENDED FOR PATIENT MOUNT)	Class IIb, Rule 10	45275
011-46110-29	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, Safeset® Reservoir, 84" (213 cm) Red Stripe Arterial Pressure Tubing and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46110-30	Transpac® IV Bifurcated Kit w/Safeset® Reservoir, 03 ml Squeeze Flush Device and Needleless Valve	Class IIb, Rule 10	45275
011-46110-39	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, Red Stripe Tubing, Macro drip (Intended For Patient Mount)	Class IIb, Rule 10	45275
011-46110-48	Bifurcated Monitoring Kit w/03 ml Flush Device, Transpac® IT, 60" (152 cm) Micro drip, Red and Blue Stripe Tubing 225 cm	Class IIb, Rule 10	45275
011-46110-49	Trifurcated Monitoring Kit w/03 ml Flush Device, Transpac® IT, 60" (152 cm) Micro drip, Clear, Red and Blue Stripe Tubing 225 cm	Class IIb, Rule 10	45275
011-46110-50	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, 60" (152cm) Macro drip, 135 cm Red Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46110-51	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, 60" (152cm) Macro drip, 150 cm Red Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46110-52	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, 60" (152cm) Macro drip, 135 cm Clear Pressure Tubing	Class IIb, Rule 10	45275
011-46110-53	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, 60" (152cm) Macro drip, 150 cm Clear Pressure Tubing	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46110-57	Transpac® IV Disposable Transducer w/3-Way Stopcock and 4-Way Stopcock	Class IIb, Rule 10	45275
011-46110-58	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, 10 ml Safeset® Reservoir and CSP	Class IIb, Rule 10	45275
011-46110-59	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device and 58" (147 cm) PT Tubing	Class IIb, Rule 10	45275
011-46110-63	Transpac® IT Trifurcated Kit w/03 ml Flush Device, 150 cm Red, Blue and Yellow Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46110-70	Transpac® IT Monitoring Kit w/03 ml Flush Device, 9" (23 cm) Tubing and Patient Mount	Class IIb, Rule 10	45275
011-46110-71	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, MicroClave, 03 ml Safeset® Reservoir and CSP	Class IIb, Rule 10	45275
011-46110-79	Single Line Transpac® IT w/03 ml Flush Device and 60" (152cm) Red Stripe PT Tubing	Class IIb, Rule 10	45275
011-46110-80	Bifurcated Transpac® IT Monitoring Kit w/03 ml Flush Devices, 60" (152cm) Red and Blue Stripe PT Tubings	Class IIb, Rule 10	45275
011-46110-81	Trifurcated Transpac® IT Monitoring Kit w/03 ml Flush Devices, 60" (152cm) Red, Blue and Yellow PT Tubings	Class IIb, Rule 10	45275
011-46110-82	Transpac® IT Kit w/30 ml Flush Device and 24" (60 cm) Red Stripe PT Tubing	Class IIb, Rule 10	45275
011-46110-85	Transpac® w/150 cm Pressure Tubing and 4 Way Stopcocks	Class IIa, Rule 2	45275
011-46110-95	Transpac IV Monitoring Kit w/03 ml Squeeze Flush Device, 55" (139 cm) PT Tubing, 8" (20cm) Ext Set w/3 Way Stopcock, Graduated Connector, Non-DEHP Tubing	Class IIb, Rule 10	45275
011-46111-10	Safeset® Blunt Cannula 18 G X 25 cm (1"/2.5 cm)	Class IIa, Rule 2	45760
011-46111-15	Add On 10 ml Safeset® Reservoir and 2 Needleless Valves Kit	Class IIa, Rule 2	45760
011-46111-19	Safeset® Reservoir w/03 ml Squeeze Flush Device and Admin Set	Class IIa, Rule 2	45760
011-46111-28	12" (30 cm) Arterial Pressure Red Stripe Tubing Extension Set Male/Female	Class IIa, Rule 2	35529
011-46111-32	Clave Sampling Port (luer connector with stopcock) w/4" (10 cm) IV Tubing	Class IIa, Rule 2	32172
011-46111-48	10" (25 cm) Red Stripe Tubing w/Needleless Valve	Class IIa, Rule 2	35529
011-46112-17	ICP Kit Single Monitoring Line w/Transpac IV, 8" (20 cm) Green Stripe PT Tubing and No Flush Device	Class IIb, Rule 10	35927
011-46112-21	Transpac IT w/10 ml Safeset Reservoir, 03 ml Flush Device, 2 CSP and Red Stripe Tubing	Class IIb, Rule 10	45275
011-46112-23	Transpac IV Monitoring Kit w/03 ml Squeeze Flush Device and 60" (152cm) Red Stripe Tubing, Pole Mount	Class IIb, Rule 10	45275
011-46112-24	Transpac IV Kit With Safeset Reservoir and Blood Sampling Port, 180 cm Tubing, Disposable Transducer, 03 ml Squeeze Flush Device and Macro drip	Class IIb, Rule 10	45275
011-46112-25	Transpac IV Bifurcated Monitoring Kit w/03 ml Squeeze Flush Device Arterial and CVP Lines	Class IIb, Rule 10	45275
011-46112-28	Transpac IT w/91 INCH (232 CM), 3 ML/HR Macro drip	Class IIb, Rule 10	45275
011-46112-32	Single Line Transpac IT Monitoring Kit w/03 ml Flush Device and 60" (152 cm) Tubing	Class IIb, Rule 10	45275
011-46112-33	Transpac IT Monitoring Kit w/ 12" (30 cm) Tubing, 03 ml Flush Device and Macro drip Patient Mount	Class IIb, Rule 10	45275
011-46112-34	Bifurcated Transpac IT Monitoring Kit w/03 ml Flush Device, 48" (122 cm) Red and Yellow Stripe Tubing	Class IIb, Rule 10	45275
011-46112-35	Transpac IT Monitoring Kit w/03 ml Flush Device, 12" (30 cm) Tubing, CSP and Patient Mount	Class IIb, Rule 10	45275
011-46112-36	Transpac IT Monitoring Kit, 72" (182cm) Tubing, 03 ml Flush Device, Macro drip	Class IIb, Rule 10	45275
011-46112-37	Transpac IT Monitoring Kit, 72" (182cm) Tubing, 03 ml Flush Device, CSP and Macro drip	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46112-38	Transpac IT Monitoring Kit w/03 ml Flush Device, 72" (182 cm) Red Stripe Tubing and Macrodrop	Class IIb, Rule 10	45275
011-46112-39	Transpac IT Monitoring Kit w/30 ml Flush Device and 12" (30 cm) Tubing	Class IIb, Rule 10	45275
011-46112-40	Transpac IT Trifurcated Monitoring Kit w/03 ml Flush Devices, 60" (152 cm) Red, Blue and Yellow Stripe Tubing and Macrodrop	Class IIb, Rule 10	45275
011-46112-41	1 Line, 1 Transducer 60" (152 cm) Red Stripe Tubing, 03 ml/hr, CSP, Macrodrop	Class IIb, Rule 10	45275
011-46112-42	Transpac IT Trifurcated Monitoring Kit w/03 ml Flush Devices, 60" (152 cm) Tubing and Macrodrop	Class IIb, Rule 10	45275
011-46112-43	Bifurcated Transpac IT Monitoring Kit w/03 ml Flush Device and 48" (122 cm) Tubing	Class IIb, Rule 10	45275
011-46112-44	Transpac IT Monitoring Kit w/03 ml Flush Device, 72" (182 cm) Red Stripe Tubing, CSP and Macrodrop	Class IIb, Rule 10	45275
011-46112-55	Transpac® IV w/03 ml Squeeze Flush Device, 60" (152 cm) Macro Admin Set, Pressure Tubing 60" (152 cm) and Stopcock Indicator Plugs	Class IIb, Rule 10	45275
011-46112-69	Transpac® IT Trifurcated Monitoring Kit w/03 ml Flush Device, 3 Needleless Valves, Red, Yellow and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46112-71	CVP Transpac® IT Monitoring Kit w/72" (182 cm) Blue Stripe TBG, Needleless Valve and 03 ml Flush Device	Class IIb, Rule 10	45275
011-46112-72	Arterial Transpac® IT Monitoring Kit w/03 ml Flush Device, 72" (183 cm) Red Stripe PT and 10" (25 cm) Red Stripe PT Extension and 1 Needleless Valve	Class IIb, Rule 10	45275
011-46112-73	CVP and Arterial Transpac® IT Bifurcated Monitoring Kit w/03 ml Flush Devices, Red and Blue Stripe PT and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46113-62	Transpac™ IV Monitoring Kit w/Safeset™ Reservoir, 03 ml Intraflo™ Flush Device, 64" (163 cm) Red Stripe Pressure Tubing, 3 Way stopcock and 79" (200 cm) Blue Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46113-63	CVP Transpac® IT Monitoring Kit, 72" (183 cm), 03 ml Flush Device, Macrodrop	Class IIb, Rule 10	45275
011-46113-72	Transpac® IT Monitoring Kit w/03 ml Flush Device, Safeset™ Reservoir, Sampling Ports and 71" (180 cm) Red Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46113-95	Transpac® IT Monitoring w/03 ml Flush Device, 30 cm (12") PT Tubing and Patient Mount	Class IIb, Rule 10	45275
011-46114-05	CVP Transpac® IV Monitoring Kit w/100 cm (39") Blue Stripe TBG, Needleless Valve and 03 ml Squeeze Flush Device	Class IIb, Rule 10	45275
011-46114-23	Transpac® IT Monitoring Kit w/03 ml Flush Device	Class IIb, Rule 10	45275
011-46114-34	Transpac® IT Monitoring Kit w/03 ml Flush Device, Safeset™ Reservoir and 60" (152 cm) PT Tubing	Class IIb, Rule 10	45275
011-46114-52	NICU Transpac® IT Monitoring Kit w/30 ml Flush Device, Blood Sampling Port and 10 cc Contamination Sheath Syringe	Class IIb, Rule 10	45275
011-46114-83	Transpac® IT Monitoring Kit 152 cm (60") w/03 ml Flush Device, Macrodrop	Class IIb, Rule 10	45275
011-46114-91	Transpac® IT Monitoring Kit w/Safeset™ Reservoir, 03 ml Flush Device, 183 cm (72") Red Stripe Pressure Tubing and Needleless Valve	Class IIb, Rule 10	45275
011-46114-92	Transpac® IT Bifurcated Kit w/03 ml Flush Device, Safeset™ Reservoir, Needleless Valve, 190.5 cm (75") Red Stripe and 183 cm (72") Blue Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46115-11	Trifurcated Transpac® IV Monitoring Kit w/03 ml Flush Device, Safeset™ Reservoir, Needleless Valves Red and Blue Stripe TBG	Class IIb, Rule 10	45275
011-46115-14	Arterial Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device and 2 Needleless Valves	Class IIb, Rule 10	45275
011-46115-15	Transpac® IT Monitoring Kit w/30 ml Flush Device and 2 Needleless Valves	Class IIa, Rule 2	45275
011-46115-21	Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, MicroClave®, 03 ml Safeset™ Reservoir and Blood Sampling Port	Class IIb, Rule 10	45275
011-46115-57	Transpac™ Monitoring Kit w/Safeset™ Reservoir, 3ml Squeeze Flush Device, Needleless Valve and MicroClave™	Class IIb, Rule 10	45275

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

PN	Description	Classification, Rule	GMDN Code
011-46116-30	Transpac® IV Monitoring Kit, 72" (182 cm) Red Stripe, Disposable Transducer, 03 ml Squeeze Flush Device, Macro drip (Pole Mount)	Class IIb, Rule 10	45275
011-46116-31	Transpac™ IV Bifurcated Monitoring Kit 72" (182 cm) Red and Blue Stripe Tubing, 2 Disposable Transducers, 2 03 ml Squeeze Flush Devices, Macro drip (Pole Mount)	Class IIb, Rule 10	45275
011-46116-32	Transpac® IV Trifurcated Monitoring Kit 72" (182 cm) Red, Blue and Yellow Stripe Tubing, 3 Disposable Transducers, 3 03 ml Squeeze Flush Devices, Macro drip (Pole Mount)	Class IIb, Rule 10	45275
011-46116-36	CVP Single Line Transpac® IV Monitoring Kit w/03 ml Squeeze Flush Device, Needleless Valve and Blue Stripe Tubing	Class IIb, Rule 10	45275
011-46116-47	Transpac® ST Monitoring Kit with 4-Way Stopcock	Class IIb, Rule 10	45275
011-46116-59	122 cm (48") Neonatal/Pediatric 03 ml Safeset™ Reservoir with Needleless Valve	Class IIa, Rule 2	45760
011-46116-80	Transpac® IT Monitoring Kit w/03 ml Squeeze Flush Device, 60" (152cm) Pressure TBG, 03 ml Syringe and MicroClave®	Class IIb, Rule 10	45275
011-46116-98	Bifurcated Transpac™ IV Monitoring Kit w/03 ml Intraflo™, Needleless Valves, Red and Blue Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46116-99	Transpac™ IV Monitoring Kit w/03 ml Intraflo™ Flush Device, Needleless Valves and Red Stripe Pressure Tubing	Class IIb, Rule 10	45275
011-46200-40	Safeset™ Reservoir Add On Kit w/183 cm (72") Pressure Tubing and Needleless Valve	Class IIa, Rule 2	45760
011-46200-49	152 cm (60") Blue Stripe Pressure Tubing M/F	Class IIa, Rule 2	35529
011-46200-66	Add On Kit w/10 ml Safeset™ Reservoir and 5 cm (2") Red Stripe PT Tubing	Class IIa, Rule 2	45760
011-46200-98	Admin Set With 03 ml Squeeze Flush Device	Class IIa, Rule 2	45275
011-46300-06	Cath Lab kit w/3 Port Manifold "ON" Handles (600 psi) Drip Chamber, Non-Vented, 1 200 cm (79") PT Tubing and 1 200 cm (79") IV Tubing	Class IIa, Rule 2	45275
011-46300-27	122 cm (48") Extension Set w/High Pressure Stopcock (600 psi) 3 Way Rotator	Class IIa, Rule 2	35529
011-46300-44	122 cm (48") Neonatal/Pediatric 03 ml Safeset™ Reservoir with Needleless Valves	Class IIa, Rule 2	45760
011-46400-30	8 Inch (20 cm) Monitoring Extension Set	Class IIa, Rule 2	35529
011-47100-01	TPIT Monitoring Kit w/3ml Flush Device, Safeset™ Reservoir, Red Stripe PT and LAD	Class IIb, Rule 10	45275
011-48000-03	Bifurcated IT Transpac™ w/3ml Flush, Macro drip, Red and Blue Stripe Tubing, 60" (152 cm)	Class IIb, Rule 10	45275
011-48000-04	Bifurcated IT Transpac™ w/3ml Flush, Macro drip, Yellow and Blue Stripe Tubing 60" (152) cm	Class IIb, Rule 10	45275
011-48100-02	Bifurcated TPIT Monitoring Kit w/3ml Flush Device, Safeset™ Reservoir, LAD, Red and Blue Stripe PT	Class IIa, Rule 2	45275
011-49100-01	Trifurcated TPIT Monitoring Kit w/3ml Flush Device, Safeset™ Reservoir, LAD, Red, Blue and Yellow Stripe PT	Class IIb, Rule 10	45275
011-C2548	ADMIN SET WITH 03 ml SQUEEZE FLUSH	Class IIa, Rule 2	45275
081-42002-13	Dual Port Intraflo Without Filter, 03 ml/hr Continuous Flush Device	Class IIa, Rule 2	35511
081-42375-01	72"(182CM) ARTERIAL PRESSURE TUBING MALE/MALE	Class IIa, Rule 2	35529
081-42582-06	Transpac® IV Disposable Transducer With Stopcocks	Class IIb, Rule 10	45275
081-42640-06	Transpac® IV Monitoring Kit With Safeset® Reservoir and Blood Sampling Port, 60" (152cm) Tubing, Disposable Transducer, 03 ml Squeeze Flush Device, Macro drip (Pole Mount)	Class IIb, Rule 10	45275
081-42650-06	Transpac® Trifurcated Monitoring Kit with Safeset® Reservoir and 2 Blood Sampling Ports, 84" (213 cm), 3 03 ml Squeeze Flush Devices, 3 Disposable Transducers, Macro drip (Pole Mount)	Class IIb, Rule 10	45275
081-42653-66	Neonatal/Pediatric Safeset® Reservoir with Needleless Valve	Class IIa, Rule 2	45760

MANUFACTURER'S DECLARATION OF CONFORMITY

Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

END OF ATTACHMENT A PRODUCT LIST

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Technical File Number 252.702 / Disposable Pressure Monitoring Devices, Kits, and Accessories

Standards Applied

Standard Reference	Standard Title
EN ISO 13485:2016	Medical Devices - Quality Management Systems
EN ISO 14971:2019	Medical devices. Application of risk management to medical devices
EN ISO 11135-1:2014/Amd 1:2018	Sterilization of health care products. Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices
EN 556-1:2001/AC:2006	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
EN 1041:2008 +A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
EN ISO 11607-1:2019	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN 15986:2011	Symbol for use in the labelling of medical devices. Requirements for labelling of medical devices containing phthalates
EN 60601-1-2:2015/A1:2021	Medical electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
EN IEC 60601-2-34:2011	Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
EN 20594-1:1993/A1:1997	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986)
ANSI/AAMI BP22	Blood Pressure Transducers
ANSI/AAMI NS28	Intracranial Pressure Monitoring
ISO 10993-10:2021	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin

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	sensitization
ISO 594-2:1998	Conical Fittings with 6 % (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 2: Lock Fittings
ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO 14698-1: 2003	Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods