

Mardi 14 février 2022,

Objet : Dispositifs classe I

Chère Cliente, Cher Client,

Le 6 janvier 2022, ICU Medical a racheté Smiths Medical. La qualité et la conformité aux normes sont des facteurs essentiels pour gagner et conserver la confiance de nos clients, et nous nous tenons aux normes les plus élevées.

Aussi, suite à cette acquisition, nous procédons à une évaluation approfondie de la conformité de tous les dispositifs Smiths Medical de classe I. Par prudence, et avec effet immédiat, nous instituons de manière proactive un blocage temporaire des expéditions de tous les produits Smiths Medical de classe I, et ce pour tous les clients de pays exigeant le marquage CE.

Ces produits peuvent toujours être utilisés en toute sécurité ; vous pouvez donc continuer à utiliser les produits que vous avez en stock. Vous pouvez également commander ces dispositifs auprès de distributeurs qui ont ces produits en stock. Nous sommes conscients des inconvénients que cette décision peut engendrer et nous vous remercions par avance de votre patience. Nous nous engageons à vous fournir des mises à jour en temps opportun, à mesure que la situation évolue.

Nous vous prions d'agréer, Chère Cliente, Cher Client, l'expression de nos sentiments les meilleurs.

Johanna Schrader
Directeur International des Affaires réglementaires,
Représentant autorisé de l'UE
Smiths Medical ASD Inc.

Dispositifs impactés par ce blocage des expéditions :

Product Family	Product Code	Description
Ambulatory Infusion Pumps	21-2131-25	CADD®-Solis – Communication Module (CM)
Ambulatory Infusion Pumps	21-2135-25	CADD®-Solis Polemount Adapter
Ambulatory Infusion Pumps	21-2165-64	CADD-Legacy® Duodopa® Pouch
Ambulatory Infusion Pumps	21-2166-24	CADD® Pump Pouch
Ambulatory Infusion Pumps	21-2167-25	CADD® Pump Pouch
Ambulatory Infusion Pumps	21-2168-25	CADD® Pump Pouch
Ambulatory Infusion Pumps	21-2169-24	CADD® Pump Pouch
Ambulatory Infusion Pumps	21-2170-64	CADD-Legacy® Duodopa® Pouch

Ambulatory Infusion Pumps	21-2171-25	CADD® Pump Pouch, Single Use
Ambulatory Infusion Pumps	21-2183-25	CADD®-Solis Polemount Swivel
Ambulatory Infusion Pumps	21-2188-25	CADD®-Solis - LockBox
Ambulatory Infusion Pumps	21-2189-25	CADD®-Solis - LockBox
Ambulatory Infusion Pumps	21-6118-24	CADD® Polemount Bracket
Ambulatory Infusion Pumps	21-6120-24	CADD® Lockable Polemount Bracket
Ambulatory Infusion Pumps	21-6212-24	CADD-Legacy® Security Shell Adapter
Ambulatory Infusion Pumps	21-6220-64	CADD-Legacy® Remote Dose
Breathing	11-1030	Ace® Aerosol Cloud Enhancer
Bronchial Hygiene and Lung Expansion	002000	Portex® Incentive Spirometer Breathing Exerciser
Convective Warming	SWU-2001	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2002	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2003	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2004	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2007	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2009	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2010	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2011	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2013	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2014L	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2014R	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2016	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2018	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2113	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-2119	Level 1® Snuggle Warm® Convective Warming Blanket
Convective Warming	SWU-9001	Snuggle Warm® Hose Adapter
Convective Warming	SWU-9002	Snuggle Warm® Hose Adapter
Convective Warming	SWU-9003	Snuggle Warm® Hose Adapter
Convective Warming	SWU-9004	Snuggle Warm® Hose Adapter
Infusion MultiPump Computer Software	22-0004-0202-51	PharmGuard® Device Reports Software
Infusion MultiPump Computer Software	22-0004-0204-25	PharmGuard® Device Reports Software
Infusion MultiPump Computer Software	22-0004-0205-25	PharmGuard® Device Reports Software
Infusion MultiPump Computer Software	22-0117-0201-25	PharmGuard® Device Interoperability Software
Infusion MultiPump Computer Software	22-0117-0202-25	PharmGuard® Device Interoperability Software
Infusion MultiPump Computer Software	22-4095-0101-51	PharmGuard® Server Software
Infusion MultiPump Computer Software	22-4095-0201-51	PharmGuard® Server Software
Infusion MultiPump Computer Software	22-4095-0204-25	PharmGuard® Server Software
Infusion MultiPump Computer Software	22-4095-0205-25	PharmGuard® Server Software
Infusion MultiPump Computer Software	22-4097-0101-51	Medfusion® Model 4000 Device Reports and Metadata
Infusion MultiPump Computer Software	22-4097-0200-51	Medfusion® Model 4000 Device Reports and Metadata
Intubation	100/503/200	Portex® Tracheostomy Tube Holder - Non-Sterile
Intubation	14-504-17	Portex® Venn Reusable Tracheal Tube Introducer
Intubation	14-504-68	Portex® Tracheal Tube Exchange Guide
Intubation	14-504-76	Portex® Tracheal Tube Exchange Guide
Intubation	69-1200	Portex® Wrap Strap
Intubation	K1000	Portex® Endotracheal Tube Holder

Intubation	K2000	Portex® Endotracheal Tube Holder
Intubation	K3000	Portex® Endotracheal Tube Holder
Patient Monitoring	1105	BCI® Airway Adapter
Patient Monitoring	1128	BCI® Nafion® Tube Extension
Patient Monitoring	1148	BCI® Filter
Patient Monitoring	1151	BCI® Airway Adapter
Patient Monitoring	1152	BCI® Airway Adapter
Patient Monitoring	1179	BCI® CO2 Absorber
Patient Monitoring	1502	BCI® Gas Calibration Cylinder
Patient Monitoring	5093	BCI® Gas Calibration Cylinder
Patient Monitoring	6122	BCI® NIBP Monitoring Accessories
Patient Monitoring	8044	BCI® Sample Lines Extension
Patient Monitoring	8061	BCI® Gas Regulator
Patient Monitoring	8075	BCI® Moisture Trap Adaptor
Patient Monitoring	8208	BCI® Filter
Patient Monitoring	8211	BCI® Sample Lines Extension
Patient Monitoring	8217	BCI® Gas Calibration Kit
Patient Monitoring	8223	BCI® Gas Calibration Adapter
Patient Monitoring	9048	BCI® Filter
Patient Monitoring	1140B	BCI® Sample Lines Extension
Patient Monitoring	1140M	BCI® Sample Lines Extension
Patient Monitoring	1153B	BCI® Airway Adapter
Patient Monitoring	1178N	BCI® Moisture Trap Adaptor
Patient Monitoring	WW1018B	BCI® SPECTRO2™ Oximeter Protective Gloves
Patient Monitoring	WW1018G	BCI® SPECTRO2™ Oximeter Protective Gloves
Patient Monitoring	WW1018R	BCI® SPECTRO2™ Oximeter Protective Gloves
Patient Monitoring	WW1018Y	BCI® SPECTRO2™ Oximeter Protective Gloves
Patient Monitoring	WW1100	BCI® Airway Adapter
Patient Monitoring	WW1140	BCI® Sample Lines Extension
Patient Monitoring	WW8030	BCI® Airway Adapter
Patient Monitoring	WW8214	BCI® Gas Accessories
Peripheral Intravenous Catheters (PIVC)	EC06	Jelco® I.V Cradles - Adult
Peripheral Intravenous Catheters (PIVC)	FC00	Jelco® I.V Cradles
Peripheral Intravenous Catheters (PIVC)	HC02	Jelco® I.V Cradles
Peripheral Intravenous Catheters (PIVC)	HC04	Jelco® I.V Cradles
Peripheral Intravenous Catheters (PIVC)	HC08	Jelco® I.V Cradles - Adult
Peripheral Intravenous Catheters (PIVC)	HC10	Jelco® I.V Cradles
Peripheral Intravenous Catheters (PIVC)	HC11	Jelco® I.V Cradles
Peripheral Intravenous Catheters (PIVC)	HC12	Jelco® I.V Cradles - Adult
Pressure Monitoring	MX1821-BCZ	Medex™ C-Fusor® Pressure Infusion - Squeeze Bulb Assembly
Pressure Monitoring	MX1821-GCZ	Medex™ C-Fusor® Pressure Infusion - Gauge
Pressure Monitoring	MX240P1CZ	Medex™ Pressure Monitoring Manifold Clamp
Pressure Monitoring	MX244P1CZ	Medex™ Pressure Monitoring Manifold Clamp
Pressure Monitoring	MX257C2CZ	Medex™ TranStar® Bracket
Pressure Monitoring	MX260CZ	Medex™ LogiCal® Bracket
Pressure Monitoring	MX260-PMCZ	Medex™ LogiCal® Patient Mount

Pressure Monitoring	MX261P1CZ	Medex™ LogiCal® Bracket
Pressure Monitoring	MX262P1CZ	Medex™ LogiCal® Bracket
Pressure Monitoring	MX263P1CZ	Medex™ LogiCal® Bracket
Pressure Monitoring	MX264CZ	Medex™ LogiCal® Bracket
Pressure Monitoring	MX267C2CZ	Medex™ LogiCal® Bracket
Pressure Monitoring	MX4705P1CZ	Medex™ Clear-Cuff® Pressure Infusor Bags
Pressure Monitoring	MX4710P1CZ	Medex™ Clear-Cuff® Pressure Infusor Bags
Pressure Monitoring	MX4805P1CZ	Medex™ C-Fusor® Pressure Infusion Devices
Pressure Monitoring	MX4806CZ	Medex™ C-Fusor® Pressure Infusion Devices
Pressure Monitoring	MX4810P1CZ	Medex™ C-Fusor® Pressure Infusion Devices
Pressure Monitoring	MX4830P1CZ	Medex™ C-Fusor® Pressure Infusion Devices
Pressure Monitoring	MX800P1CZ	Medex™ Pressure Monitoring Transducer Plate
Pressure Monitoring	MX800-SCZ	Medex™ Novastrap
Pressure Monitoring	MX900-02CZ	Medex™ NovaTrans® Pressure Monitoring Cable
Pressure Monitoring	MX900-04CZ	Medex™ NovaTrans® Pressure Monitoring Cable
Pressure Monitoring	MX901-08CZ	Medex™ NovaTrans® Pressure Monitoring Cable
Pressure Monitoring	MX901-105CZ	Medex™ NovaTrans® Pressure Monitoring Cable
Pressure Monitoring	MX901-132CZ	Medex™ NovaTrans® Pressure Monitoring Cable
Pressure Monitoring	MX901-19CZ	Medex™ NovaTrans® Pressure Monitoring Cable
Pressure Monitoring	MX901-68CZ	Medex™ NovaTrans® Pressure Monitoring Cable
Pressure Monitoring	MX901-74CZ	Medex™ NovaTrans® Pressure Monitoring Cable
Pressure Monitoring	MX961Y05CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y08	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y08L1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y08L20CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y08L2CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y118CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y126CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y130CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y132CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y19CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y19L20CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y44CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y68L20CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y68STCZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y79CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Y80CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z01P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z02STCZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z03P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z04P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z14P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z15P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z17P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z22P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z25P1CZ	Medex™ Logical® Pressure Monitoring Cable

Pressure Monitoring	MX961Z34P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z42P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z44P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z47P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z50P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z62P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z64P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z68P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z74P1	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX961Z86CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Y08STCZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Y100CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Y118CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Y126CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Y132CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z02P1	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z02STCZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z03P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z04P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z14P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z15P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z17P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z20P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z22P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z42P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z50P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z64P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z68P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX962Z70P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX963Y08CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX963Z15P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX963Z20P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX963Z42P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX963Z50P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX964Y08CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX964Z02P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX964Z20P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX964Z22P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX964Z50P1CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX964Z85CZ	Medex™ Logical® Pressure Monitoring Cable
Pressure Monitoring	MX980-02CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX980-04CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX980-14CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX980-17CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX980-20CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX980-42CZ	Medex™ TranStar® Pressure Monitoring Cable

Pressure Monitoring	MX980-50CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX980-62CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX981-105CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX981-19CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX981-22CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX981-37CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX981-44CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX981-47CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX981-64CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX981-68CZ	Medex™ TranStar® Pressure Monitoring Cable
Pressure Monitoring	MX981-69CZ	Medex™ TranStar® Pressure Monitoring Cable
Sharps Safety	4139	Jelco® Point-Lok® Sharps Safety Device
Sharps Safety	4140	Jelco® Venipuncture Needle-Pro® Needle Protection Device
Sharps Safety	4141	Jelco® Venipuncture Needle-Pro® Needle Protection Device
Sharps Safety	4142	Jelco® Venipuncture Needle-Pro® Needle Protection Device
Syringe Infusion Pumps	22-1000-51	Medfusion® Lockbox
Syringe Infusion Pumps	22-1050-51	Medfusion® Rotating/Detachable Poleclamp
Syringe Infusion Pumps	22-1051-51	Medfusion® Rotating/Detachable Poleclamp
Syringe Infusion Pumps	67-2391-010500-51	Software Update, Medfusion® 4000 Ver 1.5
Syringe Infusion Pumps	67-2449-0300-51	PharmGuard® Supported Syringes (PSS) Syringe Configuration Data
Syringe Infusion Pumps	67-2450-0105-51	Software Update, Medfusion® 4000 Ver 1.5
Syringe Infusion Pumps	67-2454-0300-51	PharmGuard® Supported Syringes (PSS) Series 2 Syringe Configuration Data
Syringe Infusion Pumps	67-2460-0003-51	Medfusion® Standard Configuration
Tracheostomy	520000	Portex® Tracheostomy Tube Holder
Tracheostomy	520001	Portex® Tracheostomy Tube Holder
Tracheostomy	520002	Portex® Tracheostomy Tube Holder
Tracheostomy	100/534/010CZ	Portex® Decannulation Cap
Tracheostomy	100/555/100	Portex® Tracheostomy Wedge
Tracheostomy	100/855/000	Portex® Blue Line Ultra® Cleaning Brush
Tracheostomy	100/855/000CZ	Portex® Blue Line Ultra® Cleaning Brush
Tracheostomy	69-0600TS	Portex® Tracheostomy Tube Strap
Tracheostomy	69-0675TS	Portex® Tracheostomy Tube Strap
Tracheostomy	69-0680TS	Portex® Tracheostomy Tube Strap
Tracheostomy	69-0685TS	Portex® Tracheostomy Tube Strap
Tracheostomy	CON15S	Bivona® Side Port Auto Control Airway Connector
Tracheostomy	DWG300	Bivona® Disconnect Wedge
Tracheostomy	REDCAP	Bivona® Tracheostomy Universal 15mm Redcap Plugs
UNKNOWN	R88	Portex® A-Clamp