

Smiths Medical ASD, Inc. "Declaration of Conformity" with Directive 93/42/EEC
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Smiths Medical ASD Inc., situated at 160 Weymouth Street, Rockland, MA USA, hereby declares that all devices listed, bearing the CE mark and released for sale after the date that this document was issued, comply with the European Medical Devices Directive 93/42/EEC of 14th June 1993 as transposed into UK law by Statutory Instrument S.I.2002 No.618 and as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 concerning medical devices as transposed into UK law by Statutory Instrument S.I. 2008: 2936 and by subsequent Directives, laws, and other national regulations.

None of the listed devices contain animal derived tissues as defined in Directive 2003/32/EC.

None of the listed devices contain medicinal substances as defined in Directive 2001/83/EC.

None of the listed devices contain human blood derivatives defined in Directive 2000/70/EC.

The EU Authorized Representative for the majority of the listed devices is Smiths Medical International Ltd., situated at Colonial Way, Watford, Herts WD24 4LG UK. For the product codes with an asterisk (*), the EU Authorized Representative is Smiths Medical International Ltd., situated at Boundary Road, Hythe, Kent, CT21 6JL

AMTAC Certifications Services Ltd has been appointed as Notified Body to undertake activities pursuant to Annex II (except section 4) in respect of the Class IIa and Class IIb devices.

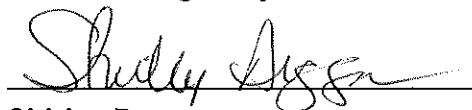
Medical Device(s):	see attached Product Schedule
Classification:	see attached Product Schedule
GMDN Code and Term:	see attached Product Schedule
Scope of Application:	Full Quality Assurance Procedures have been applied to all lots of those devices listed.

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Full Quality Management System Certificate:	AMTAC Certification Services Limited, CE-0473 Certificate Number: 171CE Annex II of the European Medical Device Directive 93/42/EEC
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Standards Applied:	see Standards Compliance for specific product family
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Authorized Signatory:



Shirley Duggan

Quality Assurance Manager / Management Representative

23 NOV 2010

Date

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Product Code Numbers	GMDN Code	GMDN Term	Class	Product Family	Product Family Description
EQ-5000-230V	36856	Heater	IIb	Convective Warming System	Convective Warming Unit
SW-2001	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Adult
SW-2002	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Pediatric
SW-2003	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Upper Body
SW-2004	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Lower Body
SW-2005	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Neonates and Small Children
SW-2006	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Premie
SW-2007	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Tube
SW-2008	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Sterile
SW-2009	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Pediatric Underbody
SW-2010	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Sterile
SW-2011	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Large Pediatric Underbody
SW-2013	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Underbody
SW-2014R	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Lateral Access
SW-2014L	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Lateral Access
SW-2015	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Upper Underbody
SW-2016	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Full Body Split Access
SW-2018	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Multi-Access
SW-2019	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Poncho

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Product Code Numbers	GMDN Code	GMDN Term	Class	Product Family	Product Family Description
SW-2019	36931	Heating pad, air	IIb	Convective Warming System	Convective Warming Blanket, Poncho
SW-4000B	36856	Heater	IIb	Convective Warming System	Convective Warming Unit, United Kingdom
SW-4000D	36856	Heater	IIb	Convective Warming System	Convective Warming Unit, Italy
SW-4000E	36856	Heater	IIb	Convective Warming System	Convective Warming Unit, Europe
SW-4000F	36856	Heater	IIb	Convective Warming System	Convective Warming Unit, Denmark
SW-4000J	36856	Heater	IIb	Convective Warming System	Convective Warming Unit, Switzerland
SW4-Hose	38442	Unclassified	IIb	Convective Warming System, Accessories	Hose for SW-4000
SW4-Hose7	38442	Unclassified	IIb	Convective Warming System, Accessories	Hose for SW-4000, 7'
SW4-HoseN	38442	Unclassified	IIb	Convective Warming System, Accessories	7' Hose for SW-4000 for use with Neonatal Blankets
SW5-Hose	38442	Unclassified	IIb	Convective Warming System, Accessories	Hose for EQ-5000
SW5-Hose7	38442	Unclassified	IIb	Convective Warming System, Accessories	Hose for EQ-5000, 7"
SW5-HoseN	38442	Unclassified	IIb	Convective Warming System, Accessories	7' Hose for EQ-5000 for use with Neonatal Blankets
SW-CL1	38442	Unclassified	IIb	Convective Warming System, Accessories	Sheet Clip for SW-3000
F3-5000	38442	Unclassified	IIb	Convective Warming System, Accessories	Filter Replacement Kit for the Equator 5000
SW-F1	38442	Unclassified	IIb	Convective Warming System, Accessories	Filter Replacement for the Snuggle Warm 3000
SW-F2	38442	Unclassified	IIb	Convective Warming System, Accessories	Filter Replacement for the Snuggle Warm 3000
H-1000 230V	38446	Warmer, blood/solution, high-flow	IIb	Fast Flow Fluid Warming Units	Fluid Warming System
H-1025 230V	38446	Warmer, blood/solution, high	IIb	Fast Flow Fluid Warming Units	Fluid Warming System

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Product Code Numbers	GMDN Code	GMDN Term	Class	Product Family	Product Family Description
H-1125 230V	38446	Warmer, blood/solution, high	Ilb	Fast Flow Fluid Warming Units	Fluid Warming System
H-1200 230V	38446	Warmer, blood/solution, high	Ilb	Fluid Warming System	Fluid Warming System
HL-290 230V	10447	Warmer, blood/solution	Ilb	Fluid Warming Systems Incorporating Programmable Electrical Medical Systems (PEMS)	Hotline 2 IV Fluid Warmer
H-30	30086	Alarm system	Ilb	Level 1 Air Detector/Clamp	Level 1 Air Detector/Clamp
H-31	30086	Alarm system	Ilb	Level 1 Air Detector/Clamp	Level 1 Air Detector/Clamp
SA-1000 230V	30086	Alarm system	Ilb	Level 1 Air Detector/Clamp	Level 1 Air Detector/Clamp
H-2	13100	Infusion regulator, pressure	Ilb	Fast Flow Accessory Equipment	Pressure Infuser
8004003	38446	Warmer, blood/solution, high	Ilb	Fast Flow replacement	O-ring Replacement Kit (for use with H-1000, H-1100 & H-12000)
F-10	35072	Filter, intravenous line	Ila	Fast Flow Infusion Set Accessories	Replacement Filter with Gas Vent
F-30	35072	Filter, intravenous line	Ila	Fast Flow Infusion Set Accessories	Replacement High flow Filter with Gas Vent
F-50	35072	Filter, intravenous line	Ila	Fast Flow Infusion Set Accessories	Replacement Filter with Gas Vent
PF-1	35072	Filter, intravenous line	Ila	Fast Flow Infusion Set Accessories	Pre-Filter -340 micron blood filter
SC-3	32172	Infusion stopcock	Ila	Fast Flow Infusion Set Accessories	High Flow 3-Way Stopcock
X-36	17501	Connector, intravenous line	Ila	Fast Flow Infusion Set Accessories	High Flow 36" Extension
Y-30	17501	Connector, intravenous line	Ila	Fast Flow Infusion Set Accessories	High Flow Y-Type Extension Line, 30"

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Product Code Numbers	GMDN Code	GMDN Term	Class	Product Family	Product Family Description
Y-INJ	17501	Connector, intravenous line	Ila	Fast Flow Infusion Set Accessories	Y-Connector/Injection
DI-50	41609	Intravenous administration set, heat exchanging	Ila	Fast Flow Infusion Sets	Disposable IV Fluid Warming Set
DI-60HL	41609	Intravenous administration set	Ila	Fast Flow Infusion Sets	Disposable IV Fluid Warming Set with insulated Patient Line
DI-65HL	41609	Intravenous administration set	Ila	Fast Flow Infusion Sets	Disposable IV Fluid Warming Set with insulated Patient Line
DI-70	41609	Intravenous administration set, heat exchanging	Ila	Fast Flow Infusion Sets	Disposable IV Fluid Warming Set
DI-75	41609	Intravenous administration set, heat exchanging	Ila	Fast Flow Infusion Sets	Disposable IV Fluid Warming Set
DI-100	41609	Intravenous administration set	Ila	Fast Flow Infusion Sets	Disposable IV Fluid Warming Set
DI-150	41609	Intravenous administration set	Ila	Fast Flow Infusion Sets	Disposable IV Fluid Warming Set
DI-300	41609	Intravenous administration set	Ila	Fast Flow Infusion Sets	Disposable IV Fluid Warming Set
DI-350	41609	Intravenous administration set	Ila	Fast Flow Infusion Sets	Disposable IV Fluid Warming Set
IR-40	41609	Intravenous administration set	Ila	Irrigating Sets	High Flow Irrigating Set
IRI-600	41609	Intravenous administration set, heat exchanging	Ila	Irrigating Sets	Disposable Irrigating Set
IRI-600B	41609	Intravenous administration set	Ila	Irrigating Sets	Disposable Irrigating Set
IR-700	41609	Intravenous administration set	Ila	Irrigating Sets	Disposable Irrigating Set

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IR-6	15585	Irrigation kit	Ila	Irrigating Sets Accessories	High Flow Irrigating Y-set adaptor
IR-7	15585	Irrigation kit	Ila	Irrigating Sets Accessories	High Flow Irrigating Y-set adaptor
PL-6	35072	Filter, intravenous line	Ila	Irrigating Sets Accessories	Replacement Patient Line for IRI-600
PL-7	35072	Filter, intravenous line	Ila	Irrigating Sets Accessories	Replacement Patient Line for IRI-700
HL-90 230V	10447	Warmer, blood/solution	IIb	Slow Flow Fluid Warming Units	Hotline Fluid Warmer
80-04-001	10447	Warmer, blood/solution	IIb	Slow Flow Fluid replacements	O-ring Replacement Kit (for use with Hotline)
L-10	35072	Filter, intravenous line	Ila	Slow Flow Infusion Sets	Hotline Gas Vent
L-70	41609	Intravenous administration set, heat exchanging	Ila	Slow Flow Infusion Sets	Hotline Fluid Warming Set
L-70 NI	41609	Intravenous administration set	Ila	Slow Flow Infusion Sets	Hotline Fluid Warming Set without Injection Port
L-270	41609	Intravenous administration set, heat exchanging	Ila	Slow Flow Infusion Sets	Hotline Fluid Warming Set without Injection Port
PC-8	17501	Connector, intravenous line	Ila	Slow Flow Infusion Sets	T-Connector, 8" Patient Lead Injection Port
YC-8	17501	Connector, intravenous line	Ila	Slow Flow Infusion Sets	8" Patient Lead with Injection Port
ES100-124	35254	Probe, thermometer, single-use	IIb	Esophageal Stethoscopes	Esophageal Stethoscope, 12 Fr.
ES100-18	35254	Probe, thermometer, single-use	IIb	Esophageal Stethoscopes	Esophageal Stethoscope, 18 Fr.
ES100-24	35254	Probe, thermometer, single-use	IIb	Esophageal Stethoscopes	Esophageal Stethoscope, 24 Fr.

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Product Code Numbers	GMDN Code	GMDN Term	Class	Product Family	Product Family Description
ES400-9	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 400 Series, 9 Fr.
ES400-12	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 400 Series, 12 Fr.
ES400-18	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 400 Series, 18 Fr.
ES400-24	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 400 Series, 24 Fr.
ES700-9	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 700 Series, 9 Fr.
ES700-12	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 700 Series, 12 Fr.
ES700-18	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 700 Series, 18 Fr.
ES700-24	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 700 Series, 24 Fr.
ES70S-9	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 70S Series, 9 Fr.
ES70S-12	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 70S Series, 12 Fr.
ES70S-18	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 70S Series, 18 Fr.
ES70S-24	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, 70S Series, 24 Fr.
ESTC-9	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, Thermocouple Type, 9 Fr.
ESTC-12	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, Thermocouple Type, 12 Fr.

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ESTC-18	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, Thermocouple Type, 18 Fr.
ESTC-24	35254	Probe, thermometer, single-use	IIB	Esophageal Stethoscopes	Esophageal Stethoscope, Thermocouple Type, 24 Fr.
FC400-8	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Pediatric 400 Series, 8 Fr.
FC400-10	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Pediatric 400 Series, 10 Fr.
FC400-12	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Pediatric 400 Series, 12 Fr.
FC400-14	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Adult 400 Series, 14 Fr.
FC400-16	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Adult 400 Series, 16 Fr.
FC400-18	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Adult 400 Series, 18 Fr.
FC70S-16	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Adult 70S Series, 16 Fr.
FC70S-18	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Adult 70S Series, 18 Fr.
FCTC-8	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Pediatric Thermocouple Type, 8 Fr.
FCTC-10	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Pediatric Thermocouple Type, 10 Fr.
FCTC-12	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Pediatric Thermocouple Type, 12 Fr.
FCTC-14	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Adult Thermocouple Type, 14 Fr.

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Product Code Numbers	GMDN Code	GMDN Term	Class	Product Family	Product Family Description
FCTC-16	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Adult Thermocouple Type, 16 Fr.
FCTC-18	34917	Catheter, urological, self-retained	IIB	Foley Catheter Temperature Probe	Foley Catheter, Adult Thermocouple Type, 18 Fr.
ER400-12	35254	Probe, thermometer, single-use	IIB	General Purpose Temperature Probes (Esophageal/Rectal)	General Purpose Probe, 400 Series, 12Fr.
ER400-9	35254	Probe, thermometer, single-use	IIB	General Purpose Temperature Probes (Esophageal/Rectal)	General Purpose Probe, 400 Series, 9Fr.
ER700-12	35254	Probe, thermometer, single-use	IIB	General Purpose Temperature Probes (Esophageal/Rectal)	General Purpose Probe, 700 Series, 12Fr.
ER700-9	35254	Probe, thermometer, single-use	IIB	General Purpose Temperature Probes (Esophageal/Rectal)	General Purpose Probe, 700 Series, 9Fr.
ER70S-12	35254	Probe, thermometer, single-use	IIB	General Purpose Temperature Probes (Esophageal/Rectal)	General Purpose Probe, 700 Series, Substitute 12Fr.
ER70S-9	35254	Probe, thermometer, single-use	IIB	General Purpose Temperature Probes (Esophageal/Rectal)	General Purpose Probe, 700 Series, Substitute 9Fr.
ERTC-9	35254	Probe, thermometer, single-use	IIB	General Purpose Temperature Probes (Esophageal/Rectal)	General Purpose Probe, Thermocouple Type, 9Fr.
ERTC-12	35254	Probe, thermometer, single-use	IIB	General Purpose Temperature Probes (Esophageal/Rectal)	General Purpose Probe, Thermocouple Type, 12Fr.
STS-201	35254	Probe, thermometer, single-use	IIB	Skin Temperature Probes	Sensor, 201 Series Neo-Therm Skin Temperature Probes (Pink) for use with Airshields C100, C200, C550, PM78s
STS-202	35254	Probe, thermometer, single-use	IIB	Skin Temperature Probes	Sensor, 202 Series Neo-Therm Skin Temperature Probe (Yellow) for use with Airshields C86, Warmers ICS; Mobile Units (most older Airshields units)
STS-203	35254	Probe, thermometer, single-use	IIB	Skin Temperature Probes	Sensor, 203 Series Neo-Therm Skin Temperature Probes (Beige) for use with Ohmeda NIC 190 ASC Incubators; Ohio Isolette

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STS-204	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, 204 Series Neo-Therm Skin Temperature Probes (Light Blue) for use with Ohmeda Incubators IC, GC, and CP; Warmers 2001, 3000
STS-205	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, 205 Series Neo-Therm Skin Temperature Probes (White) for use with Hill Rom Warmers 200 and 2000 Series, Drager
STS-206	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, 206 Series Neo-Therm Skin Temperature Probes (Lavender) for use with Hill Rom 1500A, 1250A, and 2000C
STS-207	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, 207 Series Neo-Therm Skin Temperature Probes (Orange) for use with New Airshields Equipment
STS-208	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, 208 Series Neo-Therm Skin Temperature Probes for use with Airshields Resuscitaire
STS-209	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, 208 Series Neo-Therm Skin Temperature Probes for use with Giraffe equipment
STS-400	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, 400 Series Skin Temperature Probes
STS-700	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, 700 Series Skin Temperature Probes
STS-70S	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, 70S Series Skin Temperature Probes
STS-TC	35254	Probe, thermometer, single-use	IIb	Skin Temperature Probes	Sensor, Thermocouple Type Temperature Probes
TTS-400	35254	Probe, thermometer, single-use	IIb	Tympanic Temperature Probes	Sensor, 400 Series Tympanic Temperature Probes
TTSP-400	35254	Probe, thermometer, single-use	IIb	Tympanic Temperature Probes	Sensor, 400 Series Pediatric Tympanic Temperature Probes

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TTS-70S	35254	Probe, thermometer, single-use	Ilb	Tympanic Temperature Probes	Sensor, 70S Series Tympanic Temperature Probes
TTSP-70S	35254	Probe, thermometer, single-use	Ilb	Tympanic Temperature Probes	Sensor, 70S Series Pediatric Tympanic Temperature Probes
TTSP-TC	35254	Probe, thermometer, single-use	Ilb	Tympanic Temperature Probes	Sensor, Pediatric Thermocouple Type Tympanic Temperature Probes
TTS-TC	35254	Probe, thermometer, single-use	Ilb	Tympanic Temperature Probes	Sensor, Thermocouple Type Temperature Probes
22-2000*	31266	Spirometer, incentive	Ila	Respiratory Lung Expansion Devices	Coach 2 for Kids® Incentive Spirometer
22-2500*	31266	Spirometer, incentive	Ila	Respiratory Lung Expansion Devices	Coach 2® 2500 ml Incentive Spirometer
22-2501*	31266	Spirometer, incentive	Ila	Respiratory Lung Expansion Devices	Coach 2® 2500 ml Incentive Spirometer w/one way valve
22-4000*	31266	Spirometer, incentive	Ila	Respiratory Lung Expansion Devices	Coach 2® 4000 ml Incentive Spirometer
22-4001*	31266	Spirometer, incentive	Ila	Respiratory Lung Expansion Devices	Coach 2® 4000 ml Incentive Spirometer
22-1200*	31266	Spirometer, incentive	Ila	Respiratory Lung Expansion Devices	DHD CliniFlo® Low Flow Breathing Exerciser
27-0050*	11634	Exerciser, respiratory	Ila	Bronchial Hygiene Devices	acapella choice® mouthpiece
27-7000*	11634	Exerciser, respiratory	Ila	Bronchial Hygiene Devices	acapella choice® vibratory PEP device
27-9000*	11634	Exerciser, respiratory	Ila	Bronchial Hygiene Devices	acapella duet® w/small volume Nebulizer and tubing
27-9001*	11634	Exerciser, respiratory	Ila	Bronchial Hygiene Devices	acapella duet® vibratory PEP device