

DECLARATION OF CONFORMITY CERTIFICATE

MANUFACTURER:

Dale Medical Products, Inc.
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1-508-695-9316
SRN: US-MF-000019061

EUROPEAN REPRESENTATIVE:

Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41
D-30175 Hannover
Germany
SRN: DE-AR-000005430

Name of Product(s)

See Attached List (two pages)

Classification:

Class 1, Low Risk, Non-Sterile and Non-Measuring

We, the manufacturer, herewith declare that the above mentioned products meet the provisions of the EU Medical Device Regulation (EU 2017/745) for Medical Devices. All supporting documentation is retained on the premises of the manufacturer.



By: Raymond Gruneberg
Director of Quality and Regulatory Affairs
For Dale Medical Products, Inc.
February 3, 2025
Franklin, MA USA



PRODUCT NAME	PRODUCT NUMBER	BASIC UDI-DI	DESCRIPTION	INTENDED USE
NasoGastric Tube Holders	160	08176120216064	Fits most	To hold nasogastric and aspiration tubes in the nares.
	161	08176120216166	Small	To hold nasogastric and aspiration tubes in the nares.
	163	0817612021636A	One Leg	To hold nasogastric and aspiration tubes in the nares.
Scrape-n-Suction Tongue Cleaner	220	0817612022205V	Tongue Scraper	To remove biofilm from the top surface of the tongue as a supplement to normal daily oral hygiene care.
Tracheostomy Tube Holders	240	08176120224063	240 Blue® – 1" wide, fits up to 19½" neck	To provide secure positioning and minimize movement of the tracheostomy tube for all patients.
	241	08176120224165	241 PediPrints® – 1" wide, fits up to 18" neck	To provide secure positioning and minimize movement of the tracheostomy tube for all patients.
	242	08176120224267	242 PediPrints® – ¾" wide, fits up to 9" neck	To provide secure positioning and minimize movement of the tracheostomy tube for all patients.
	244	0817612022446B	244 Blue® Bariatric – 1 ½" wide, fits to 28" neck	To provide secure positioning and minimize movement of the tracheostomy tube for all patients.
Endotracheal Tube Holders	270	0817612022706C	Stabilock fits tubes 7.0 – 10.0 mm	To secure and stabilize Endotracheal tubes.
	280	0817612022806F	BREEZELOCK with Tube Track fits tubes 7.0-10.0 mm	To secure and stabilize Endotracheal tubes.
Foley Catheter Holders	150	0817612021505Z	Hold-n-Place® Adhesive Patch	To provide secure positioning and minimize movement of the Foley catheter for all patients.
	316	0817612023166B	Hold-n-Place® Legband	To provide secure positioning and minimize movement of the Foley catheter for all patients.
	330	08176120233065	Hold-n-Place® Bariatric Legband	To provide secure positioning and minimize movement of the Foley catheter for all patients.
Nasal Dressing Holder	600	0817612026006B	Fits most	To hold nasal dressings and packing following rhinoplasty, septoplasty, sinus surgery, facial trauma, and nose bleeds.
Transducer Holders	620	0817612026206H	3 Tab, Fits standard size transducers	To position and secure up to three transducers to help ensure correct waveform readings.
	622	0817612026226M	2 Tab, Fits large transducers	To position and secure up to two transducers to help ensure correct waveform readings.
Armboards	650	0817612026506S	Large, fits most adults	To position and secure the wrist to prevent unwanted movement when using arterial and peripheral (intravenous) lines.
	651	0817612026516U	Medium, fits small adults/geriatrics	To position and secure the wrist to prevent unwanted movement when using arterial and peripheral (intravenous) lines.

PRODUCT NAME	PRODUCT NUMBER	BASIC UDI-DI	DESCRIPTION	INTENDED USE
	652	0817612026526W	Small, fits infants/pediatrics	To position and secure the wrist to prevent unwanted movement when using arterial and peripheral (intravenous) lines.
	653	0817612026536Y	X-Small PediPrints	To position and secure the wrist to prevent unwanted movement when using arterial and peripheral (intravenous) lines.
IV Armor	675	0817612026757A	One size fits most	To maximize IV patency while protecting the site from patient tampering.
Post-Surgical Bras	701	0817612027016J	Small, fits 32-34" (A-B)	To provide support and compression immediately following breast surgery.
	702	0817612027026L	Medium, fits 34 - 36" B - D	To provide support and compression immediately following breast surgery.
	703	0817612027036N	Large, fits 36-38" B - D	To provide support and compression immediately following breast surgery.
	704	0817612027046Q	X-Large, fits 38 - 44" B - D	To provide support and compression immediately following breast surgery.
	705	0817612027056S	XX-Large 46 - 54" C - E	To provide support and compression immediately following breast surgery.
	706	0817612027066U	XXX-Large 54-60" E-I	To provide support and compression immediately following breast surgery.
Abdominal Binders	525	0817612025256N	2 Panel 6" Wide, Stretches to fit 72-127cm (28-50")	Abdominal Binder, provides support and comfort following surgical procedures.
	410	08176120241064	3 Panel 9" Wide, Stretches to fit 76-114 cm (30-45")	Abdominal Binder, provides support and comfort following surgical procedures.
	411	08176120241166	3 Panel 9" Wide, Stretches to fit 117-157cm (46 - 62")	Abdominal Binder, provides support and comfort following surgical procedures.
	418	0817612024186L	3 Panel 9" Wide, Stretches to fit 152-191cm (60 - 75")	Abdominal Binder, provides support and comfort following surgical procedures.
	810	0817612028106Q	4 Panel 12" Wide, Stretches to fit 76-114cm (30 - 45")	Abdominal Binder, provides support and comfort following surgical procedures.
	811	0817612028116S	4 Panel 12" Wide, Stretches to fit 117-157cm (46 - 62")	Abdominal Binder, provides support and comfort following surgical procedures.
	818	08176120281878	4 Panel 12" Wide, Stretches to fit 152-191cm (60 75")	Abdominal Binder, provides support and comfort following surgical procedures.
	820	0817612028206T	4 Panel 12" Wide, Stretches to fit 183-239cm (72 - 94")	Abdominal Binder, provides support and comfort following surgical procedures.
	920	0817612029206Y	5 Panel, 15" Wide, Stretches to fit 183-239 (72 - 94")	Abdominal Binder, provides support and comfort following surgical procedures.