



# DECLARATION OF CONFORMITY CERTIFICATE

## MANUFACTURER:

Dale Medical Products, Inc.  
40 Kenwood Circle, Suite 7  
Franklin, MA 02038-3298  
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.**

A handwritten signature in black ink, reading "Raymond Gruneberg".

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. |
| <b>IV Armor</b>           | 675            | 0817612026757A | One size fits most                                      | To maximize IV patency while protecting the site from patient tampering.  |
| <b>Post-Surgical Bras</b> | 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.  |
| <b>Abdominal Binders</b>  | 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.   |