**General Description:**

**Non-pneumatic anti-shock garment (NASG)**

**Product Description:**
The non-pneumatic anti-shock garment (NASG) is used to manage the uncontrollable postpartum haemorrhage (PPH) and to keep women alive until they can get the treatment they need.

- Lightweight, flexible and comfortable for the wearer.
- Reusable
- No metal parts: safe for X-rays and MRIs

**Material:**
Made of a lightweight neoprene garment and Velcro.

The NASG must allow perineal access so that examinations and vaginal procedures can be performed without it being removed.

**Shape:**
- Made in the shape of trousers divided into five or six segments for ease of application to different parts of lower body below the diaphragm with Velcro fasteners.
- The segment 1 must consist of 2 pieces to be used in each ankles,
- The segment 2 must consist of 2 pieces to be used in each calf,
- The segment 3 must consist of 2 pieces to be used in each thigh,
- The segment 4 must consist of 1 piece to be used around the pelvis,
- The segment 5 and/or 6 must consist of 1 piece to be used around the abdomen/umbilicus. This segment must apply extra compression with a small foam ball.

**Sizes:** Required small size.

- The garment must be able to apply 30 to 50 mm Hg of pressure to the lower body pressure.
- Lifetime: At least 40 uses.
- Washable in washer machine.

**Supplied with:**
- Manufacture's instructions for use in English.

**Packaging and labelling:**
- Packaged with full instructions in English.

**Labelling on the primary packaging:**
- Name and/or trade mark, and address of the manufacturer.
- Manufacturer's product reference.
- Type of product and main characteristics.
- Information for product-specific storage conditions (e.g., temperature, pressure, light, humidity, etc.).

**Regulation & conformity requirements:**
- QMS ISO 13485 certificate with identified EC acknowledged notifying body
- CE mark, EC certificate with identified EC acknowledged notifying body, or, FDA approval with 510k clearance
- Labeling according to ISO 15223
- Declaration of conformity
- CE mark conforming to Medical Device Directive 93/42/EEC

**Item specific safety standards:**
- ISO13934-1 and ISO 6330 Tensile strength loss after washing
- Supplied with: sufficient instructions for use (including the details of the sufficient cleaning procedure).
Classification:
Class I-Medical Device Directive 93/42/EEC