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 aground 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.
- Life time: 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