Ultrasound Technologies Ltd

EC Declaration of Conformity

Ultrasound Technologies Ltd as manufacturers of the products listed below declare they are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC + 2007/47/EC concerning Medical Devices.

- PD1 series of fetal and vascular Doppler's including:-

  PD1 audio fetal Doppler
  PD1+ fetal Doppler with FHR display.
  PD1 combi Doppler (PD1 with interchangeable 2,3,5,8MHz transducers)
  PD1+ combi Doppler (PD1+ with interchangeable 2,3,5,8MHz transducers)
  PD1/PD1+ combi probe 2MHz
  PD1/PD1+ combi probe 3MHz
  PD1/PD1+ combi probe 5MHz
  PD1/PD1+ combi probe 8MHz
  PD1dwr waterbirth Doppler (PD1+ with waterproof probe)
  PD1v vascular Doppler – Pencil or Flat probe
  PD1cv vascular Doppler (PD1 with standard 5 or 8MHz probes)
  Fetatrack 120 – (PD1)
  Fetatrack 120+ – (PD1+)
  Vascutrack 120 – (PD1cv)
  Freeplay FHRM

- Fetatrack DD250 Fetal & Vascular doppler

  Fetatrack DD250 probe 2MHz
  Fetatrack DD250 probe 3MHz
  Fetatrack DD250 probe 5MHz
  Fetatrack DD250 probe 8MHz

and are in conformity with all or parts of the national standards transposing harmonised standards:

- BS EN 60601-1:2006+A12:2014
- BE EN 60601-1-2:2015
- BS EN 60601-2-37:2008
- BS EN 60601-1-6:2010
- BS EN ISO 14971:2012

The products are classified class 2a and are subjected to the conformity procedure set out in Annex II (excluding section 4) of Council Directive 93/42/EEC + 2007/47/EC under the supervision of Notified Body Number 1639 SGS Belgium NV, SGS House, Noorderlaan 87, 2030 Antwerpen, Belgium.

Standards Applied:

- BS EN ISO 13485:2016

EU Authorised Representative:

- MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany

For and on behalf of Ultrasound Technologies Ltd

Managing Director
23rd February 2022

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