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 - Gima foetal Doppler G2002.
  PD1+ - Gima foetal Doppler D2003 with display.
  PD1 combi - Gima V2000 Doppler without probe.
  PD1 combi probe 8MHz - Gima 8MHz vascular probe for V2000 Doppler.
  PD1 combi probe 5MHz - Gima 5MHz vascular probe for V2000 Doppler.
  PD1 combi probe 2MHz - Gima 2MHz gyn probe for V2000 Doppler.
  PD1dwr waterbirth Doppler (PD1+ with waterproof probe) – Gima foetal Doppler D2005 with display – waterproof.
  PD1vc 5 vascular Doppler – Gima V2005 vascular Doppler with 5MHz fixed probe.
  PD1vc 8 vascular Doppler – Gima V2008 vascular Doppler with 8MHz fixed probe.

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
1st March 2021

Ultrasound Technologies Ltd
Lodge Way
Portskewett
Caldicot
South Wales NP26 5PS
United Kingdom.

Tel: +44 (0) 1291 425425
Fax: +44 (0) 1291 427093
Email: ultratec@doppler.co.uk
Webpage: www.doppler.co.uk
Company Registered in England No. 2665356
Registered Office:
Foresters House, Itton, Chepstow, NP16 6BZ