



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 Doppler's including:-

Device	UDI-DI	Gima Reference
PD1 audio fetal Doppler	5060337640046	Gima foetal Doppler – 29502 - G2002
PD1+ fetal Doppler with FHR display	5060337640053	Gima foetal Doppler - 29503 - D2003 with display
PD1dwr waterbirth Doppler (PD1+ with waterproof probe)	5060337640060	Gima foetal Doppler – 29505 - D2005 with display – waterproof
PD1 combi Doppler with interchangeable 2,3,5,8MHz probe.	5060337640077	Gima V2000 – 33123 - Doppler without probe
PD1/PD1+ combi probe 2MHz	5060337640213	Gima gyn probe – 33126 - for V2000 Doppler.

- PD1 series of vascular Doppler's including:-

Device	UDI-DI	Gima Reference
PD1cv vascular Doppler (PD1 with standard 5 or 8MHz probes)	5060337640107 - 5M 5060337640206 - 8M	Gima V2005 – 33120 - vascular Doppler with 5MHz fixed probe. Gima V2008 – 33121 - vascular Doppler with 8MHz fixed probe.
PD1/PD1+ combi probe 5MHz	5060337640237 - 5M	Gima vascular probe – 33127 5M for V2000 Doppler.
PD1/PD1+ combi probe 8MHz	5060337640244 - 8M	Gima vascular probe – 33128 8M for V2000 Doppler.



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

- BS EN 60601-1:2006+A2:2021
- BS EN 60601-1-2:2015
- BS EN 60601-2-37:2008
- BS EN 60601-1-6:2010
- BS EN ISO 14971:2019+A11:2021

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

Product Risk Classification	Class 2a under rule 10
EU Authorised Representative	MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany
Directive 93/42/EEC	Certificate GB19/964514 Issued SGS Belgium NV - NB 1639

For and on behalf of Ultrasound Technologies Ltd

Managing Director
24th March 2023