**Doppler apparatus, pocket type**

Product description:

Doppler, foetal heart rate (FHR) detector, with accessories To be used in basic health infrastructures for routine examination of foetal life, from about 10-12 weeks gestation through to delivery.

Transducer frequency, approximately 2MHz

Self-test is performed each time the device is switched

Large LCD shows, foetal heart rate in beats per minute (bpm), pulse indicator and sound volume level

Built-in loudspeaker with volume adjustment

System reports, with audio-visual alert: operational status, malfunctions and low battery

Advanced noise/disturbance suppression system assures quality diagnostic sound

Regular size, approx: 18 to 20 cm.

Light weight, handheld, easy to operate and carry

(pocket size)

Supplied with:

1 x Soft carry bag easy to clean

1 x Instructions manual (instructions for assembly, use and maintenance in English, French, and Spanish)

Instructions for use:

To be used in basic health infrastructures for routine examination of foetal life, from about 10-12 weeks gestation through to delivery.

Doppler foetal heart rate detector should be operated by an adequately trained person only.

Clean and disinfect the device after each use.

Doppler foetal heart detector must be used and maintained according manufacturer's instructions.

Accessories/ spare parts/consumables:

Ultrasound gel, batteries

Packaging & Labelling:

Unit presentation: 1 (one) Doppler, FHR detector, with accessories and Instructions for use.

Symbols used according ISO 15223

CE with notified body number

Regulation & conformity requirements:

CE mark conforming to Medical Device Directive (MDD) 93/42/EEC

CE certificate ( for Class IIa, with Notified Body Number)

Classification:

Class IIa (MDD 93/42/EEC)

Safety & product Standards:

Must comply with following standards

IS0 13485: 2003

IEC 60601-1:2005;

IEC 60601-1-1:2000

IEC 60601-1-2:2007;

IEC 62366:2007

IEC 61266:1994

Environmental requirements:

Rohs compliance

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