

## General Description:

# Wind-up Doppler, foetal heart rate (FHR) detector, with accessories

### Product Description:

Doppler, foetal heart rate (FHR) detector. 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

LCD shows: foetal heart rate in beats per minute (bpm) and battery status

Built-in loudspeaker

Battery operated

Battery charger: AC 100-240 V/≈50 Hz and Hand crank

### Supplied with:

1 x Instructions manual (instructions for assembly, use and maintenance text-free pictorial based (i.e. line-drawings only) or in English, French, Spanish and, if possible, Rohingya)

### 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,

Soft carry bag easy to clean

### 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 certificate according to Medical Device Directive (MDD) 93/42/EEC (for Class IIa)

The device has to be registered in Bangladesh

### Classification

Class IIa (MDD 93/42/EEC) or Class C (GHTF)

### Safety & product Standards:

Must comply with following standards

IEC 60601-1:2005;

IEC 60601-1-1:2000

IEC 60601-1-2:2007;

IEC 62366:2007

IEC 61266:1994

Manufacturer is certified to ISO 13485: 2003