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CTG Paper

Instructions For Use

Device Classification:

This product shall be classified into class 1 according to Medical Device Directive 93/42/EEC and 2007/47/EC Rule 1.

Device Description:

CTG paper is a heat sensitive and a graph paper with international measurements of cardiotocograph cycle. Each small square measures 1mm by 1mm. Every fifth horizontal / vertical line is thicker and divides paper onto square 5mm by 5mm. Paper Recording CTG is to be used on CTG Machine.

Applications:

CTG machines

Intended Used:

In medicine (obstetrics), cardiotocography (CTG) paper is used as technical means of recording (-graphy) the fetal heartbeat (cardio-) and the uterine contractions (-toco-) during pregnancy, typically in the third trimester. The machine used to perform the monitoring is called a cardiotocograph, more commonly known as an electronic fetal monitor (EFM).

Instructions of Use:

The fixing of the paper recording CTG into printing devices is differed from different printing devices. User shall refer to instruction on label for recommended model.

For thermal reaction to take place, the heat sensitive side should in touch with printing head.

Indications:

Results printed on the medical chart can be used for detecting normal/ abnormal heartbeat of patients.

Contraindications:

Thermal medical recording chart shall not be use if it has change to black, because this shows thermal reaction already taken place.

Warnings:

Thermal medical recording chart did not contain any hazardous substances and dangerous mechanical move parts, there is no any warning needed when using the products.

Precautions:

These are no any significant potential undesirable and serious outcomes (death, injury or serious adverse events) to the patient/user, or side effects from the use of this product thermal paper, under normal conditions, no any precautions is needed.

Potential Adverse Effects:

These are no any significant potential undesirable and serious outcomes (death, injury or serious adverse events) to the patient/user, or side effects from the use of this product thermal paper, under normal conditions.

Legal manufacturer:

Global SCP Medical Systems Pte. Ltd., Singapore