

EC DECLARATION OF CONFORMITY



MANUFACTURER

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MEDICAL DEVICE – INTENDED USE AND MEDICAL PURPOSE

Goldtrace Fetal Spiral Electrode is a tool used at childbirth. Goldtrace Fetal Spiral Electrode is a disposable sterile instrument for use on patients requiring fetal heart rate monitoring. Goldtrace Fetal Spiral Electrode is a sterile single-use device, sterilized with ethylene oxide.

BRAND NAME

Article Name: Goldtrace Fetal Spiral Electrode Article no: CNS000004

CLASSIFICATION

Goldtrace Fetal Spiral Electrode is a single-use invasive product intended for use on patients requiring fetal heart rate monitoring. Due to the penetration of the skin on the fetal head, it is classified as a surgically invasive product to be used in body orifice (of the mother) and intended for short-term (≤ 24 h) use.

It is a medical device product, used for diagnostic purposes, which, in combination with other products, surveys a physiological process. The Goldtrace Fetal Spiral is intended to be connected to an electronic monitor using a reusable cable.

Goldtrace is classified as a class IIa product according to Rule 7. As no other of the exemptions under Rule 7 applies, the product is a Class IIa device.

CONFORMITY ASSESSMENT

Medical Device Directive 93/42/EEC as amended by 2007/47/EC according to annex 7.

MARK OF COMPLIANCE



DECLARATION

Wing Plast AB declare the compliance of the medical device concerned with the Swedish Medical Devices Act (1993:584) and the regulation LVFS 2003:11 as amended by LVFS 2009:18 of the Medical Products Agency. Hereby, the medical device complies with requirements of the corresponding Medical Device Directive 93/42/EEC as amended by 2007/47/EC.

Any modification to the device, not authorized by us, will invalidate this declaration.

VALID FROM

Date: 2019-07-31

MANUFACTURER'S SIGNATURE

Smålandsstenar 2019-07-31, Lena Nurbo, QA Sign:

A handwritten signature in blue ink, appearing to read 'Lena Nurbo'.

This manufacturer's declaration certifies the compliance with the law in Sweden and the EC Directive. Conditions of guarantee and liability are dealt within our General conditions of sale.