

Declaration of Conformity

Manufacturer's Name Huntleigh Healthcare Ltd
Diagnostic Products Division

Manufacturer's Address 35 Portmanmoor Road
Cardiff, UK
CF24 5HN

Products Covered

Device Name : Baby Dopplex BD4000XS-2

Device Description : Fetal Monitor (ante-partum and intra-partum use)

Project Number : HD714 **Device Classification:** Class IIb

Model Number(s) : BD4000XS-2 (fetal monitor only)
BD4000AXS-2 (fetal monitor + ante-partum accessory set)
BD4000IXS-2 (fetal monitor + intra-partum accessory set)

I, the undersigned, hereby declare that the medical devices specified above comply with the Essential Requirements in Annex I of EC Directive 93/42/EEC (as amended by 2007/47/EC), and the technical documentation detailed in the **HD714** Technical File, as held by the Project Manager at the address above.

This declaration is supported by:

Quality system approval to Annex II (Full Quality Assurance System) of EC Directive 93/42/EEC (as amended by 2007/47/EC). Issued by Lloyds Register Quality Assurance Ltd as detailed in Certificate Number LRQ 0943523/B

Signed: PP Cashin **Date:** 22 March 2010

Full Name: Peter Cashin

Position: Managing Director
Huntleigh Healthcare-Diagnostic Products Division

ATITIKIMO DEKLARACIJA

Gamintojo pavadinimas: Huntleigh Healthcare Ltd
Diagnostic Products Division

Gamintojo adresas: 35 PORTMANMOOR ROAD
CARDIFF, JK
CF24 5HN

Produktai:

Aparato pavadinimas: Baby Dopplex BD4000XS-2

Aparato aprašymas: **Fetal Monitor** (Vaisiaus monitorius)

Projekto Nr.: HD714 **Aparato klasė:** IIb

Modelio Nr.: BD4000XS-2 (Vaisiaus monitorius)
BD4000AXS-2 (Vaisiaus monitorius su priedais iki gimdymo)
BD4000IXS-2 (Vaisiaus monitorius su priedais po gimdymo)

Aš, žemiau pasirašęs, šiuo dokumentu pareiškiu, kad aukščiau paminėta medicininė įranga atitinka pagrindinius EC Direktyvos 93/42/EEC I priedo reikalavimus bei techninę dokumentaciją **HD714** „Technical File“, saugomą kompanijoje.

Priedai prie pareiškimo:

Kokybės sistemos patvirtinimas pagal EC Direktyvos 93/42/EEC II Priedą, kaip nurodyta sertifikate Nr. LRQ0943523/B.

Pasirašytas: /parašas/ Data: 2010 m. kovo mėn. 22 d.

Vardas, pavardė: Peter Cashin

Pareigos: Direktorius