PHILIPS

CE 0366

DECLARATION OF CONFORMITY

Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard Str.2
71034 Böblingen
Germany

Declares under our sole responsibility that the product:

Product Name	IntelliSpace Perinatal Rev. H.00
Product Model Number or Designator	866131, 866132, 866133, 866138
Starting Revision	Release Code RC H.00.10
Device Classification	Class IIa (Rule 10, Annex IX)
Global Medical Device Nomenclature Code (GMDN)	36230 (866131, 866132, 866133)
Product Options/Accessories	All options and accessories as described in the accompanying documents

to which this Declaration relates is in conformity with the provisions of Council Directive: 93/42/EEC (Medical Devices Directive).

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II-Section 3.2 of the Medical Device Directive. Copies of the Quality System certificates are available upon request.

Name/Address of Notified Body: VDE Testing & Certification Institute,
Merianstr. 28, D-63069 Offenbach/Main, Germany

Supplementary Information:
The application software of this product was tested in a typical configuration of a Philips IntelliSpace Perinatal system as described in the manufacturer's accompanying documents. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the accompanying documentation.

Signature:

Date: 08th Apr-2013

Printed Name: Hauke Schik
Title: Director Quality & Regulatory Affairs

Place of Issue: Böblingen