CE 0413
CE 0979

DECLARATION OF CONFORMITY

Manufacturer's Name: Invivo Corporation
Manufacturer's Address: 12501 Research Parkway
Suite 100
Orlando, FL 32826
USA

Declares, that the product

Product Name: 3160 MRI Patient Monitoring System (Precess)

Model Number(s): 3160

Starting Revision, Date code, SN, Lot Number: February 4, 2006

Product Options:

3160	MRI Patient Monitoring System (Precess)
3160 DCU	Remote Display Controller Unit
3160 WPU	Wireless Process Unit
3160-1	Network Option
3160-2	Voltage Option
3160-3	Language Option
3160-4	Recorder Option
3160-5	Gas Analysis Option
3160-6	ECG Option
3160-7	SPO2 Option
3160-8	Enhanced ECG Option
3160-9	Respiration Option
3160-10	NIBP Option
3160-11	O2 measurement Option
3160-12	Invasive Pressure Option
3160-13	Communications Option
3160-14	Neonatal Option
3160-15	Temperature Option
3160-16	Mounting Option

to which this declaration relates is in conformity with Annex I Essential Requirements of the Council Directive:

93/42/EEC (LVFS 2003:11)

"Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

to which this declaration relates is in conformity with Annex III Essential Requirements of the Council Directive:

1995/5/EC

"Council Directive of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity" (R&TTE Directive).

The Manufacturer is certified by Intertek ETL SEMKO AB (0413) to EN ISO 13485 and Annex II-Section 3.2 of Directive 93/42/EEC. Copies of the Quality System certificates are available upon request.

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The product is Class IIb according to Annex IX of Directive 93/42/EEC.

The Global Medical Device Nomenclature Code (GMDN) is 33586.

The Manufacturer is certified by Intertek ETL SEMKO (0979) to Annex IX of Directive 1995/5/EC.

Supplementary Information:
The product was tested in a typical configuration as described in the Manufacturer's accompanying documents.

Add standards here :
EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-8, EN 60601-2-27, EN 60601-2-30, EN 60601-2-34, EN 60601-2-49, EN ISO 9919, EN 1060-1, EN 1060-3, EN 12470-4, EN ISO 10993-1, EN ISO 14971, EN ISO 21647

Orlando, 12 August, 2008

Rusty Kelly
Quality and Regulatory Manager
Invivo Corporation

Authorized EU-representative: Philips Medizin Systeme Böblingen GmbH, Hewlett-Packard Str. 2, 71034 Böblingen, Germany