

Declaration of Conformity



Equipment Type(s): **PHS6000**

Product Codes(s): **PHS6000GB01, PHS6000AU01**

Europe: The responsible company declares the equipment in compliance with Council Directive 93/42/EEC (MDD), Council Directive 2004/108/EC (EMC), Council Directive 2006/95/EC (Safety/LVD), Council Directive 1999/5/EC (R&TTE), Council Directive 94/62/EC (Packaging Directive), and Council Directive 2002/95/EC (RoHS); and that the equipment is labelled in compliance with Council Directives 2002/96/EC (WEEE) and 2006/66/EC (Batteries).

CE marking affixed for the first time: 2008

Australia / New Zealand : This is a declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian *Therapeutic Goods (Medical Devices) Regulations 2002* relating to the stated devices. Each kind of medical device complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Classification: Class I

GMDN code: 32547 Telemetry system, physiological signal

Supplier Code N-232, ABN: 59 001 798 214, ACN: 001 798 214

This Declaration of Conformity is issued by **Intel Corporation**, which is solely responsible for the declared compliance.

Place of Issue / Declaring Company Address:

Intel Corporation
1900 Prairie City Road
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TGA Sponsor in Australia:

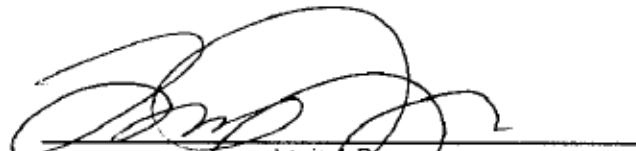
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Louis J. Burns
Vice President, General Manager of Digital Health Group

Louis J. Burns is the Manufacturer's Representative, with the authority of Intel Corporation management to make this Declaration.

Date of Issue: 12 Jun 2009

The equipment described above is declared to be in conformity with the following applicable national and international standards. The conformity is valid ONLY when the equipment is used in a manner consistent with the manufacturer's recommendations and the reference documents.

Document no.: Date of Issue	Title
EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996	Medical Electrical Equipment Part 1 : General requirements for safety
IEC 60601-1:1988 + A1:1991 + A2:1995	Medical Electrical Equipment Part 1 : General requirements for safety
IEC 60601-1-1:2000	Medical Electrical Equipment Part 1 – 1: General Requirements for Safety - Collateral Standard: Safety requirements for medical electrical systems
UL 60601-1:2006	Safety for Medical Electrical Equipment
EN 60601-1-2:2001 + A1:2006	Medical Electrical Equipment Part 1 – 2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility
IEC 60601-1-2:2007	Medical Electrical Equipment Part 1 – 2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility
CISPR 11:2004 + A2:2006	Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement
IEC 60950-1:2001	Safety of Information Technology Equipment [CB Certificate issued]
EN 60950-1:2001	Safety of Information Technology Equipment
EN 55022:2006 + A1:2007, Class B	Information Technology Equipment – Radio Disturbance Characteristics
CISPR 22:2005 + A1:2005 + A2:2006	Information Technology Equipment – Radio disturbance characteristics – Limits and methods of measurements
EN 55024:1998 + A1:2001 + A2:2003	Information Technology Equipment – Immunity Characteristics
CISPR 24:1997 + A1:2001 + A2:2002	Information Technology Equipment – Immunity Characteristics – Limits and methods of measurements
EN 61000-3-2:2006	Information Technology Equipment – Harmonic Current Emissions
IEC 61000-3-2:2005	Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN 61000-3-3:1995 + A1:2001 + A2:2005	Information Technology Equipment – Flicker
IEC 61000-3-3:2005	Electromagnetic compatibility (EMC) – Part 3-3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
EN 300 328:2006	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive
EN 301 489-17:2002	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for 2,4 GHz wideband transmission systems, 5 GHz high performance RLAN equipment and 5,8 GHz Broadband Data Transmitting Systems
EN 50371:2002	Generic standard to demonstrate the compliance of low power electronic and electrical apparatus with the basic restrictions related to human exposure to electromagnetic fields (10 MHz - 300 GHz) – General public
FCC, 47 CFR Part 15, Class B digital device	Radio Frequency Devices - Subpart B – Unintentional Radiators
FCC, 47 CFR Part 15, Bluetooth Class I	Radio Frequency Devices – Subpart C – Intentional Radiators
ICES-003 Issue 4 – Feb 2004, Class B	Interference-Causing Equipment Standards – Digital Apparatus
RSS-210 Issue 6 – Nov 2005	Low-power Licence-exempt Radiocommunications Devices (All Frequency Bands): Category I Equipment
CAN/CSA-C22.2 No. 601-1-m90:2005	Medical Electrical Equipment Part 1 : General requirements for safety
AS/NZS3200.1:1998	Medical Electrical Equipment Part 1 : General requirements for safety-Parent Standard
AS/NZS3200.1.2:2005	Medical Electrical Equipment Part 1.2 : General requirements for safety-Collateral Standard: Electromagnetic Compatibility-Requirements and Tests
AS/NZS 4268:2008	Radio Equipment and Systems – Short Range Devices – Limits and Methods of Measurement
Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) - RPS No. 3:2002	Radiation Protection Standard for Maximum Exposure Levels to Radiofrequency Fields – 3 kHz to 300 GHz (RPS3)

Council Directive 1999/5/EC (R&TTE) Member State Declaration Translations

Česky [Czech]	Intel Corporation tímto prohlašuje, že tento PHS6000 je ve shodě se základními požadavky a dalšími příslušnými ustanoveními směrnice 1999/5/ES.
Dansk [Danish]	Undertegnede Intel Corporation erklærer herved, at følgende udstyr PHS6000 overholder de væsentlige krav og øvrige relevante krav i direktiv 1999/5/EF.
Nederlands [Dutch]	Hierbij verklaart Intel Corporation dat het toestel PHS6000 in overeenstemming is met de essentiële eisen en de andere relevante bepalingen van richtlijn 1999/5/EG.
English	Hereby, Intel Corporation, declares that this PHS6000 is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.
Eesti [Estonian]	Käesolevaga kinnitab Intel Corporation seadme PHS6000 vastavust direktiivi 1999/5/EÜ põhinõuetele ja nimetatud direktiivist tulenevatele teistele asjakohastele sätetele.
Deutsch [German]	Hiermit erklärt Intel Corporation, dass sich das Gerät PHS6000 in Übereinstimmung mit den grundlegenden Anforderungen und den übrigen einschlägigen Bestimmungen der Richtlinie 1999/5/EG befindet.
Ελληνική [Greek]	ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Intel Corporation ΔΗΛΩΝΕΙ ΟΤΙ PHS6000 ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 1999/5/ΕΚ.
Magyar [Hungarian]	Alulírott, Intel Corporation nyilatkozom, hogy a PHS6000 megfelel a vonatkozó alapvető követelményeknek és az 1999/5/EC irányelv egyéb előírásainak.
Suomi [Finnish]	Intel Corporation vakuuttaa täten että PHS6000 tyyppinen laite on direktiivin 1999/5/EY oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.
Français [French]	Par la présente Intel Corporation déclare que l'appareil PHS6000 est conforme aux exigences essentielles et aux autres dispositions pertinentes de la directive 1999/5/CE.
Íslenska [Icelandic]	Hér með lýsir Intel Corporation yfir því að PHS6000 er í samræmi við grunnkröfur og aðrar kröfur, sem gerðar eru í tilskipun 1999/5/EC
Italiano [Italian]	Con la presente Intel Corporation dichiara che questo PHS6000 è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 1999/5/CE.
Latviski [Latvian]	Ar šo Intel Corporation deklarē, ka PHS6000 atbilst Direktīvas 1999/5/EK būtiskajām prasībām un citiem ar to saistītajiem noteikumiem.
Lietuvių [Lithuanian]	Šiuo Intel Corporation deklaruoja, kad šis PHS6000 atitinka esminius reikalavimus ir kitas 1999/5/EB Direktyvos nuostatas.
Malti [Maltese]	Hawnhekk Intel Corporation, jiddikjara li dan PHS6000 jikkonforma mal-ħtiġijiet essenzjali u ma provvedimenti oħrajn relevanti li hemm fid-Dirrettiva 1999/5/EC.
Norsk [Norwegian]	Intel Corporation erklærer herved at utstyret PHS6000 er i samsvar med de grunnleggende krav og øvrige relevante krav i direktiv 1999/5/EF.
Polski [Polish]	Niniejszym Intel Corporation oświadcza, że PHS6000 jest zgodny z zasadniczymi wymogami oraz pozostałymi stosownymi postanowieniami Dyrektywy 1999/5/EC
Português [Portuguese]	Intel Corporation declara que este PHS6000 está conforme com os requisitos essenciais e outras disposições da Directiva 1999/5/CE.
Slovensky [Slovak]	Intel Corporation týmto vyhlasuje, že PHS6000 spĺňa základné požiadavky a všetky príslušné ustanovenia Smernice 1999/5/ES.
Slovensko [Slovenian]	Intel Corporation izjavlja, da je ta PHS6000 v skladu z bistvenimi zahtevami in ostalimi relevantnimi določili direktive 1999/5/ES.
Español [Spanish]	Por medio de la presente Intel Corporation declara que el PHS6000 cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 1999/5/CE.
Svenska [Swedish]	Härmed intygar Intel Corporation att denna PHS6000 står i överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 1999/5/EG.