

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the **Australian Therapeutic Goods (Medical Devices) Regulations 2002** relating to the stated device.

Reference: QCT PRO Bone Mineral Densitometry

Legal Manufacturer: Mindways Software Inc.
Business Address: 3001 South Lamar Blvd;
Suite 302, Austin,
Texas 78704,
United States America

Facility: Mindways Software Inc.
3001 South Lamar Blvd;
Suite 302, Austin,
Texas 78704,
United States America

Medical Device(s): QCT PRO Bone Mineral Densitometry

Refer to Attached Schedule (model number/s)

Classification (per TGA): Class I (*Schedule 2 Section 5.1 of the Therapeutic Goods (Medical Devices) Regulations 2002*)

GMDN Code and Term:

Code	Term
40874	An individual software program or group of programs, routines or algorithms that add specific image processing and/or analysis capabilities to a bone absorptiometry or densitometry system configuration. A basic set of applications programs and routines are included with such computer controlled imaging systems and they can be upgraded to correct programming errors or to add new system capabilities. Some applications software programs or program packages must be combined specific hardware or firmware accessories or configurations in order to function as intended. Applications program packages are typically identified by a proprietary name and "version" or "upgrade" number

Scope of Application:

Batch range commenced with QCTPRO Version 4.1
Build 20060620

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

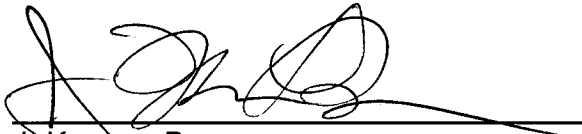
Full Quality Management System Certificate:

L 0543792-01
Annex V of the Directive 93/42/EEC

Standards Applied: (European Harmonised standard)

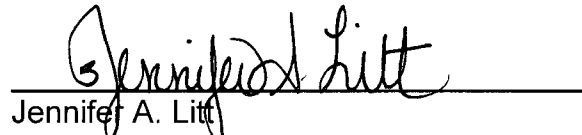
- EN ISO 13485:2003
- EN ISO 980:2003

Authorized Signatory



J. Keenan Brown
Mindways Software Inc.
3001 South Lamar Blvd;
Suite 302, Austin,
Texas 78704,
United States America

8/6/07
Date



Jennifer A. Litt
Director, Quality Assurance
Mindways Software Inc.
3001 South Lamar Blvd;
Suite 302, Austin,
Texas 78704,
United States America

Aug 6, 2007
Date

Attached Schedule

Model Number/s	Product Description
19019	QCTPRO 3D Spine & CTXA Hip Package – Australia OEM