# A SEMINAR INVITATION

**TITLE**

## UPDATES ON ISO 10993
### TEST MATRICES

**VENUE:**
**SEMINAR HALL, INSTITUT BIOLOGI SISTEM (INBIOSIS), UKM BANGI**

**DATE:**
**23rd OCTOBER 2007**

### Introduction

The ISO 10993 series of standards covering biological evaluation of medical devices are well established and regulatory authorities worldwide require compliance to this standard. In Europe, compliance with EN ISO 10993 standards is the easiest way to meet the essential product safety requirements of the Medical Device Directive. Several new parts in the series have been developed which promote a new philosophy of biological evaluation, especially parts 17 & 18. In addition, a major revision of ISO 10993 is needed to incorporate a risk management approach and better coordinate the full set of the existing 19 parts in the series. This interactive seminar will provide practical opportunities for the application of these new standards and the new approach to biological evaluations.

### Speakers

**Pn Fadilah Baharin**
Director General, Standards Malaysia
Ministry of Science, Technology and Innovations

**Prof Dr James M. Anderson**
Chairman of the ISO 10993-1 Technical Committee on "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process"

### Tentative Programme

0830-0900 : Registration

0900-0910 : Welcoming address

0910-0940 : (Malaysian Medical Device Standards)
**Pn Fadilah Baharin**

0940-1000 : Tea break

1000-1100 : (Latest updates on ISO 10993 standards)
**Prof James Anderson**

1100-1130 : Q & A and closing

* As places for the seminar are limited to only 40 participants, your prompt confirmation to attend is most appreciated. Please register by completing the attached form and return the same by fax or email on or before **17th October 2007**.

**Who should attend**
Medical device QA managers, distributors, regulatory affairs executives, students, scientists and clinicians undertaking medical device R & D.

**Contact details**
The Secretariat (ISO 10993 Seminar)
Makmal Bioserasi,
Institut Biologi Sistem (INBIOSIS),
Universiti Kebangsaan Malaysia,
43600 Bangi, Selangor.
Tel: 603-8921 4279/4280/4284
Fax: 603-8921 4281
E-mail: isoseminar@gmail.com

Universiti Kebangsaan Malaysia
National University of Malaysia

**Organised by:**
Makmal Bioserasi,
INBIOSIS, UKM Bangi
In collaboration with
Biocompatibility & Toxicology Laboratory,
Faculty of Allied Health Sciences, UKM Kuala Lumpur.