

***Memorandum of Understanding***  
*between*  
***ISO***  
*and the*  
***Global Harmonisation Task Force for Medical Devices***  
*related to the work of*  
***ISO/TC 194, Biological evaluation of medical devices***

***Recognising*** that ISO TC 194 is the International Organisation for Standardization (ISO) technical committee responsible for standardization in the field of biological evaluation of medical and dental materials and devices encompassing biological test methods applicable to those materials and devices, including standardization in the field of clinical investigations of medical devices in humans;

Recognising that the objective of the Global Harmonisation Task Force (GHTF) is to encourage convergence at the global level in the evolution of regulatory systems for medical devices in order to protect public health and facilitate trade, and that the GHTF achieves this by developing an international consensus to develop equivalent systems with a common basis for how regulatory practices and decisions are carried out with respect to medical devices;

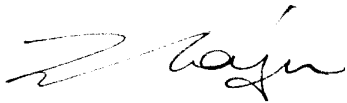
ISO and the GHTF establish this agreement with the following goals:

- Promote communication between the two organisations;
- Avoid duplication of work efforts where possible;
- Provide formal and coordinated regulatory voice to ISO TC 194;
- Promote the fit of International Standards for biological evaluation, including the ISO 10993 series and ISO 14155 (Clinical investigation), to worldwide regulatory needs where applicable;
- Utilise the expertise and resources of the ISO TC 194 efforts to improve the efficiency of regulatory activities in the service of promoting public health; and
- Promote knowledge of the GHTF and its work to ISO TC 194 and the national bodies that are involved in the regulation of medical devices.

ISO and the GHTF agree on the following activities:

1. GHTF will inform ISO TC 194 of the needs for and potential role of voluntary consensus International Standards specific to the medical device industry sector and ISO TC 194 will provide input to the GHTF to help it meet its aims and objectives.
2. ISO TC 194 will allow representatives of the GHTF to participate in meetings of the technical committee with a status equivalent to that of a Category A liaison organisation, including the right to nominate experts to participate in relevant working groups. GHTF will allow representatives of ISO TC 194 to be appointed to participate in its work at Study group level.
3. To avoid duplication of work, the Chairs of ISO TC 194 and the GHTF or their designates will confer before either initiates new work to consider the implications to both parties and the preferred venue of the work to be conducted.

This Agreement shall remain in effect until such time as one or the other party requests its termination, normally giving six months written notice in order to hold discussion about the termination and as a courtesy.

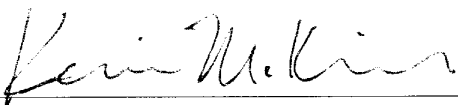


Georgette LALÈS

Chair, GHTF

10 Nov. 2005

Date



ISO Secretary-General

10 Nov 2005

Date

for