

# *Memorandum of Understanding*

## *Between ISO/TC 210 and the*

# *Global Harmonization Task Force*

*Recognizing* that ISO/TC 210 is the ISO technical committee responsible for standardization in the field of quality management and corresponding general aspects for medical devices, with a strategic objective to develop standards and guidance that effectively address the needs of regulatory authorities and manufacturers;

*Recognizing* that the objective of the Global Harmonization 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 relative to medical devices;


*ISO/TC 210 and the GHTF establish this agreement with the following goals:*

- Promote communication between the two organizations;*
- Avoid duplication of work efforts where possible;*
- Provide a formal and coordinated regulatory voice to TC 210;*
- Promote the fit of international standards to worldwide regulatory needs where applicable;*
- Utilize the expertise and resources of the TC 210 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 TC 210 and the national bodies that are involved in the regulation of medical devices.*

ISO/TC 210 and the GHTF agree on the following activities:

1. GHTF will inform ISO/TC 210 of the needs and potential role for voluntary consensus international standards specific to the medical device industry sector and ISO/TC 210 will provide input to the GHTF to help it meet its aims and objectives.
2. ISO/TC 210 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 organization, including the right to nominate experts to participate in relevant working groups. GHTF will allow representatives of ISO/TC 210 to participate in its work, at both the Task Force and Study Group level.
3. To avoid duplication of work, the two organizations will confer before either initiates new work to consider the implications to both parties and the preferred venue for 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 termination and as a courtesy.



Robert Allen  
Chairman of ISO/TC 210

29 June 1999  
Date



Elizabeth D. Jacobson  
Chair, GHTF

29 June 1999  
Date



Lawrence D. Eicher  
ISO Secretary-General

14 July 1999  
Date