

# Implementation of the GHTF Model for Device Regulation

## The Australian Experience

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# The Framework

- Essential Principles
- Classification Rules
- Conformity Assessment Procedures
- Use of standards



# Implementation

- Conformity assessment by the TGA required for
  - Australian manufacturers
  - Devices of animal/microbial/recombinant origin
  - Devices incorporating a medicine
- CE certification generally accepted for other devices
  - Application audit for Class III and AIMD
- Must have DoC to Australian requirements



# Preferred Model

- Implementation through MoUs, MRAs
- Ensures assessment to Australian requirements
- Minimises regulatory burden
- Facilitated by adoption of GHTF model



# Issues

- Adoption of standards
  - Mapping against EPs
  - Mandatory vs non-mandatory
  - Updating issues
- Differences in classification (between jurisdictions)
  - Actual differences
  - Differences in interpretation
  - Borderline products
- Differences in definitions
- Third party issues



Thank you



TGA

