



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

# Standards orders and medical devices

## What is a standard order

The Australian medical devices legislation creates a system of non-mandatory medical device standards orders (MDSO) and conformity assessment standards orders (CASO) that can be used to demonstrate compliance with a set of essential principles for safety, quality and performance, or conformity assessment (CA) procedures. These standards replaced the system of mandatory TGOs that existed for therapeutic devices under the old regulatory system.

The new legislation creates the medical device standards and CA standards as "matters specified in the order published in the gazette". The "matters" include the list of selected international or Australian standards or monographs from the British Pharmacopoeia, European Pharmacopoeia or US Pharmacopeia, but the order must also specify how the CA procedures and the essential principles are demonstrated by the standard, i.e. which clauses demonstrate compliance with essential principles or the CA procedures. Additional or alternative "matters" may also be specified in the order.

## Compliance with a standard order is not mandatory

There are no mandatory standards under the new regulatory system. Instead, medical devices must comply with a set of essential principles for quality, safety and performance of medical devices. The legislation also sets out Australian CA procedures, requirements for comparable overseas regulator evidence (<https://www.tga.gov.au/node/289428>), and options available to manufacturers.

## Why comply with a standard order

While there are no mandatory standards under the new regulatory system, the use of standards referenced in an MDSO or CASO is encouraged because where these standards exist, their use is the best method to demonstrate compliance with the Australian requirements. **Use of these**

**standards is not mandatory**, but if they are used, compliance with the essential principles or CA procedures that they have been deemed to address is assumed.

## Standards orders and other instruments

Current notices, determinations and standards orders are available at: [Medical devices notices & standards orders \(https://www.tga.gov.au/node/287259\)](https://www.tga.gov.au/node/287259).



## 原文

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