

## EXPLANATORY STATEMENT

**Subject: MEDICAL DEVICE STANDARDS ORDER NO. 3 – Medical Devices  
Required to be Sterile**

*Section 41CB, Therapeutic Goods Act 1989*

### **OUTLINE**

Medical Device Standards Order No. 3 – Medical Devices Required to be Sterile (MDSO 3) is an Order made by the delegate of the Minister for Health and Ageing under section 41CB of the *Therapeutic Goods Act 1989* (the Act).

This Order specifies relevant medical device standards relevant to medical devices that are required to be sterile, whether the device is to be sterilised by the manufacturer prior to release or to be supplied in a non-sterile state but packaged in such a way that it can be sterilised at a later stage following supply.

MDSO 3 was signed by the delegate of the Minister on 20 February 2003 and notified in the Commonwealth Gazette No. GN 9 on 5 March 2002. MDSO 3 commenced on the day it was gazetted.

### **BACKGROUND**

The Act provides for the establishment and maintenance of a national system of controls relating to the quality, safety and efficacy of therapeutic goods that are used in Australia or exported from Australia.

Section 41CB of the Act provides the Minister, or the Minister's delegate, with the power to determine medical device standards and to also determine that medical devices that comply with these standards are to be treated as complying with specified parts of the essential principles.

The essential principles set out the requirements relating to the safety and performance characteristics of medical devices that must be complied with before a device can be imported, supplied or exported. Compliance with applicable medical device standards is not required, but it is one way to establish compliance with the essential principles. If a manufacturer chooses to apply a medical device standard, and this is applied correctly, the device is presumed to comply with the parts of the essential principles set out in the Order (section 41BH of the Act).

This Order determines medical device standards by reference to published standards in three areas: qualification of a device as "sterile", packaging, and validation of sterilisation processes. It is essential, as determined by the Order, that all three aspects are applied in combination for the final level of sterility to be achieved.

The requirements for devices that are to be supplied "sterile" are set out in Schedule 1 of the Order and the requirements for devices which are intended for sterilisation following supply are set out in Schedule 2 of the Order.

The validation of steam sterilisation procedures requires compliance with ISO 11134: 1994 or EN 554: 1994 and microbiological validation in accordance with AS EN 556.1-2002.

## **REGULATION IMPACT STATEMENT**

Compliance with the proposed medical device standards is voluntary and members of industry may choose alternative means to demonstrate compliance with the Essential Principles. All stakeholders, including industry and Standards Australia have been consulted during the development of the proposed new regulatory system for medical devices. There was overall support for the adoption of international standards. The Office of Regulation Review assessed the proposal for voluntary standards and, as it is not prohibitive either in terms of costs or time delays, the proposal is considered to be non-regulatory and as such a Regulatory Impact Statement is not required.