EXPLANATORY STATEMENT

Subject: MEDICAL DEVICE STANDARDS ORDER (STANDARDS FOR MEDICAL DEVICES REQUIRED TO BE STERILE) 2008

Section 41CB, Therapeutic Goods Act 1989

OUTLINE

Medical Device Standards Order (Standards for Medical Devices Required to be Sterile) 2008 (MDSO (Sterile Devices) 2008) 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).

MDSO (Sterile Devices) 2008 revokes and replaces Medical Device Standards Order No. 3 – *Medical Devices Required to be Sterile* (MDSO 3) that was made on 20 February 2003 and commenced upon its gazettal on 5 March 2003. MDSO 3 of 2003 specified particular standards as medical device standards for 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 (Sterile Devices) 2008 introduces new standards for quality assurance techniques for the manufacture of kinds of medical devices that are intended by the manufacturer to be supplied in a sterile state. The new standards are based on the following updated standards:

- **EN 556-2: 2003** *Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 2: Requirements for aseptically processed medical devices;*
- **EN ISO 11607-1: 2006** *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems;*
- **EN ISO 11607-2: 2006** *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*
- **EN ISO 11135-1: 2007** *Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*;
- **AS/NZS ISO 11137-1: 2006** which is identical to **ISO 11137-1: 2006** *Sterilization of health care products – Radiation – Part 1: Requirements for validation and routine control – Radiation sterilization;*
- **AS/NZS ISO 11137-2: 2006** *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose;*
- **AS/NZS ISO 11137-3: 2006** *Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects;*
- **EN ISO 17665-1: 2006** *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;*
- **EN ISO 11737-1: 2006** *Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of micro-organisms on products*
- **EN ISO 11737-2: 2000** *Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process*
- **ISO 13408-1: 2008** *Aseptic processing of health care products – Part 1: General requirements*
- **ISO 13408-2: 2003** *Aseptic processing of health care products – Part 2: Filtration*

- **ISO 13408-3: 2006** *Aseptic processing of health care products – Part 3: Lyophilization*
- **ISO 13408-4: 2005** *Aseptic processing of health care products – Part 4: Clean-in-place technologies*
- **ISO 13408-5: 2006** *Aseptic processing of health care products – Part 5: Sterilization in place*
- **ISO 13408-6: 2005** *Aseptic processing of health care products – Part 6: Isolator systems*
- **ISO 14937: 2000** *Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development of routine control of a sterilization process for medical devices*
- **EN ISO 17664: 2004** *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*

Electronic or hard copies of all of the above AS and ISO standards can be purchased on-line from SAI Global Limited, which is accessible at the following website: http://www.saiglobal.com.

MDSO (Sterile Devices) 2008 was signed by the delegate of the Minister on 14 November 2008 and commenced on the day after it was registered on the Federal Register of Legislative Instruments.

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 authorises the Minister, or the Minister's delegate, by written instrument called an Order, to determine medical device standards for kinds of medical devices set out in the Order and to determine that medical devices of those kinds that comply with the standard are to be treated as complying with those parts of the essential principles specified in the standard.

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 set out in the Order, 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).

MDSO (Sterile Devices) 2008 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 MDSO (Sterile Devices) 2008 and the requirements for devices which are intended by the manufacturer to be sterilised before they are supplied are set out in Schedule 2 of MDSO (Sterile Devices) 2008.

CHANGES TO STANDARDS

International 'ISO' and 'EN' device standards are living documents that are developed and constantly being updated by groups of international experts. Australian representatives are involved in some of these committees. There is extensive consultation on the ISO and EN standards during their development and subsequent review. With both industry and the TGA seeking to optimise Australia's position in the global device market, it is imperative that Australia's standards do not fall out of step with the international market.

Updates to international device standards reflect changes to international best practice as well as the emergence of new technologies and new manufacturing procedures. Where relevant the latest international standards are adopted by leading regulators including Australia, Europe, the USA and Canada.

Australia will very quickly fall behind if it fails to adopt the latest international standards. In the longer term not keeping up with changes to the relevant international standards will lead to a unique regulatory system in Australia, making regulatory compliance more difficult and costly for importers and/or exporters of medical devices into Australia. The updated standards referenced in MDSO (Sterile Devices) 2008 reflect the current relevant international standards for sterile devices.

CONSULTATION

Key industry stakeholders including the Medical Industry Association of Australia (now the Medical Technology Association of Australia), the Australian Dental Industry Association and AusBiotech were consulted on the adoption of an updated version of MDSO 3 (the updated MDSO 3) during January-February 2008. Industry groups supported the adoption of these standards.

The updated MDSO 3 referenced ISO 13408-1: 1998 which in June 2008 was updated to ISO 13408-1: 2008 *Aseptic processing of health care products – Part 1: General requirements.* The TGA therefore further updated this Order to also reference ISO 13408-1:2008, with a proposal to phase out ISO 13408-1: 1998, in September 2009, in line with the European timeframes. A further round of consultation on this proposal took place in July-August 2008. Industry groups supported the adoption of the updated standard.

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.

APPLICATION OF THE *LEGISLATIVE INSTRUMENTS ACT 2003* (THE LIA)

Under paragraph 6(d)(i) of the LIA, an instrument is a legislative instrument for the purposes of the LIA if it is declared to be a disallowable instrument under legislation in force before the

commencement of the LIA. This determination is a legislative instrument and it is subject to tabling and disallowance in the Parliament under sections 38 and 42 of the LIA, respectively.