

COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

MEDICAL DEVICE STANDARDS ORDER (STANDARDS FOR NATURAL LATEX RUBBER CONDOMS) 2008

I, LARRY KELLY, delegate of the Minister for Health and Ageing for the purposes of section 41CB of the *Therapeutic Goods Act 1989* and acting under that section, DETERMINE:

- (a) that the matters specified in the relevant standards or parts of those standards specified in column 2 of an item in the Schedule constitute a medical device standard for Natural Latex Rubber Condoms, subject to the conditions (if any) set out in column 3 of that item of the Schedule, and
- (b) that medical devices of those kinds that comply with the standard specified in column 2 are to be treated as complying with those parts of the essential principles set out in Schedule 1 of the Therapeutic Goods (Medical Devices) Regulations 2002 and that are specified in column 4 of the relevant item of the Schedule.

This Order commences on the day after it is registered on the Federal Register of Legislative Instruments (FRLI).

Dated this 14th day of November 2008

Signed
Larry Kelly
Delegate of the Minister for Health and Ageing

Schedule

1 Item No.	2 Medical Device Standard	3 Conditions	4 Essential Principle
1	<p>ISO 4074: 2002 <i>Natural latex rubber condoms – Requirements and test methods, including Technical Corrigendum 1: 2003, but not Technical Corrigendum 2: 2008, constitute the standard for natural latex rubber condoms, subject to the modifications set out below:</i></p> <p>In addition to ISO 4074: 2002 the following applies in relation to condom labelling claims:</p> <p>1. All condoms The following claims may be included on either the outside consumer package or a leaflet contained within the consumer package:</p> <ul style="list-style-type: none"> i. condoms can help reduce the risk of pregnancy; ii. condom use may help reduce the risk of transmission of HIV/AIDS and other sexually transmitted infections (STIs)” <p>2. Condoms containing nonoxynol 9 In relation to the labelling of, and package inserts for, condoms containing nonoxynol 9:</p> <ul style="list-style-type: none"> a. Any claim for “added protection” shall specify that this claim is limited only to added protection against pregnancy. b. Claims implying that the addition of nonoxynol 9 helps reduce or prevent HIV/AIDS or sexually transmitted infections (STIs) shall not be included. c. The label or package insert shall bear the following information: “The presence of nonoxynol 9 has not been shown to reduce the risk of transmission of HIV/AIDS or other sexually transmitted infections (STIs).” 		Schedule 1, clauses 2, 3, 4, 5, 6, 7 (except 7.4), 8.4, and 9.2.