

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).” 		<p>Schedule 1, clauses 2, 3, 4, 5, 6, 7 (except 7.4), 8.4, and 9.2.</p>