
Female condoms — Requirements and test methods

AMENDMENT 1

Préservatifs féminins — Exigences et méthodes d'essai

AMENDEMENT 1





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This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

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Clause 15.3.3, item f)

Replace the phrase:

“if the manufacturer makes more than one size”

with:

“nominal width and nominal length of the female condom”.

Annex G

Add the following new subclause as G.2.7 and renumber the existing G.2.7 as G.2.8.

G.2.7 Test method verification

If required, verification that the test method is working correctly shall be confirmed by making holes in a number of individual containers using a hypodermic syringe needle with a diameter in the range 0,25 mm to 0,35 mm. Closely inspect the needle and individual container to confirm that the needle has completely penetrated right through the packaging material into the individual container.

A hypodermic needle in specified size range can become blunt after making as few as two holes. If a needle fails to penetrate into the individual container it should be replaced. If there is a failure to detect a hole made in the individual container the test should be repeated using a new needle before concluding that the test is not working.

Annex K

Add the following new subclause as K.4 and renumber the existing K.4 as K.5.

K.4 Test method verification

If required, verification that the test method is working correctly shall be confirmed by making holes in a number of female condoms using a hypodermic syringe needle with a diameter in the range 0,25 mm to 0,35 mm. Holes should be made near the closed end, in mid body and near the open end of the test condoms. Closely inspect the needle and condom to confirm that the needle has completely penetrated right through the material and into the condom.

