Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical — Exigences et méthodes d'essai
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The committee responsible for this document is ISO/TC 84, Devices for administration of medicinal products and catheters.

This second edition cancels and replaces the first edition (ISO 9626:1991), which has been technically revised. It also incorporates the Amendment ISO 9626:1991/Amd 1:2001.

The main changes to the previous edition of ISO 9626 introduced by this revision are the following:

a) addition of specifications for stainless steel needle tubing for metric sizes 0,18 mm, 0,2 mm 0,23 mm and 0,25 mm and to reflect the introduction of thinner tubing to allow greater comfort when injecting, particularly for infants and in paediatric use;

b) addition of wall thickness designations beyond regular-walled and thin-walled tubing;

c) addition of minimum inner diameters for additional items where possible;

d) revision of the means of specifying the steels to be used;

e) revision of the table of tubing dimensions and stiffness parameters.

Introduction

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.