Health Canada Santé Canada

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Notice

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Subject: Announcement of Changes to the Therapeutic Products Directorate's List of Recognized Standards for Medical Devices

Health Canada is pleased to announce changes to the Therapeutic Products Directorate's (TPD) List of Recognized Standards for medical devices.

The changes consist of:

a. 11 new standards to be added;
b. 27 new editions of currently recognized standards to replace previous editions;
c. 6 standards to be removed.

The TPD G*uidance Document on Recognition and Use of Standards under the Medical Devices Regulations* is posted on the Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/md_gd_standards_im_ld_normes-eng.php.

For further information on the List of Recognized Standards, please contact:

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Canada

Health Canada Santé Canada

List of Recognized Standards for Medical Devices

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Canada

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ISO 13959:2009 Concentrates for haemodialysis and related therapies
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CLSI MM17-A:2008 Verification and validation of multiplex nucleic acid assays; Approved guideline
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ISO 23640:2011 In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

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ASTM F75-12 Standard specification for cobalt-28chromium-6molybdenum alloy castings and casting alloy for surgical implants (UNS R30075)
ASTM F90-09 Standard specification for wrought cobalt-20chromium-15tungsten-10nickel alloy for surgical implant applications (UNS R30605)
ASTM F136-12 Standard specification for wrought titanium-6aluminum-4vanadium ELI (Extra Low Interstitial) alloy for surgical implant applications (UNS R56401)
ASTM F138-08 Standard specification for wrought 18chromium-14nickel-2.5molybdenum stainless steel bar and wire for surgical implants (UNS S31673)
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ASTM F560-08 Standard specification for unalloyed tantalum for surgical implant applications (UNS R05200, UNS R05400)
ASTM F562-07 Standard specification for wrought 35cobalt-35nickel-20chromium-10molybdenum alloy for surgical implant applications (UNS R30035)
ASTM F620-06 Standard specification for alpha plus beta titanium alloy forgings for surgical implants
ASTM F621-08 Standard specification for stainless steel forgings for surgical implants
ASTM F648-07e1 Standard specification for ultra-high-molecular weight polyethylene powder and fabricated form for surgical implants
ASTM F688-05 Standard specification for wrought cobalt-35 nickel-20 chromium-10 molybdenum alloy plate, sheet, and foil for surgical implants (UNS R30035)
ASTM F799-11 Standard specification for cobalt-28chromium-6molybdenum alloy forgings for surgical implants (UNS R31537, R31538, R31539)
ASTM F899-12 Standard specification for wrought stainless steel for surgical instruments

ASTM F961-08 Standard specification for 35cobalt-35nickel-20chromium-10molybdenum alloy forgings for surgical implants (UNS R30035)
ASTM F1088-04a (R2010) Standard specification for beta-tricalcium phosphate for surgical implantations
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ASTM F1108-04 (R2009) Standard specification for titanium-6aluminum-4vanadium alloy castings for surgical implants (UNS R56406)
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