

Medical Device Testing Standards

ISO 5840-1:2015

Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements

M6 Heart Valve Tester

MP3 Pulse Duplicator

ISO 5840-2:2015

Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes

M6 Heart Valve Tester

MP3 Pulse Duplicator

ISO 5840-3:2013

Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques

M6 Heart Valve Tester

MP3 Pulse Duplicator

ISO 7198:2016

Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches

DCT Compliance Tester

SVP-24 Stent Tester

UST Stent Tester

SD 542
100617



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ISO 12417-1:2015

Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements

SVP-24 Stent Tester

UST Stent Tester

CDT-5 Coating Durability Tester

CDT-20 Coating Durability Tester

APT Acute Particulate Tester

M6 Heart Valve Tester

ISO 14708-5:2010

Implants for surgery — Active implantable medical devices — Part 5: Circulatory support devices

PVAD Pulsatile VAD Tester

ISO/TS 17137:2014

Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants

SVP-24 Stent Tester

UST Stent Tester

CDT-5 Coating Durability Tester

CDT-20 Coating Durability Tester

APT Acute Particulate Tester

ISO 25539-1:2017

Cardiovascular implants — Endovascular devices — Part 1: Endovascular prostheses

SVP-24 Stent Tester

UST Stent Tester

ISO 25539-2:2012

Cardiovascular implants — Endovascular devices — Part 2: Vascular stents

SVP-24 Stent Tester

UST Stent Tester

CDT-5 Coating Durability Tester

CDT-20 Coating Durability Tester

APT Acute Particulate Tester

AAMI TIR42

Evaluation of Particulates Associated with Vascular Medical Devices

APT Acute Particulate Tester

ASTM F2394 - 07 (2017)

Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System

APT Acute Particulate Tester

ASTM F2477-07

Standard Test Methods for *in vitro* Pulsatile Durability Testing of Vascular Stents

SVP-24 Stent Tester

UST Stent Tester

CDT-5 Coating Durability Tester

CDT-20 Coating Durability Tester

ASTM F2743-11

Standard Guide for Coating Inspection and Acute Particulate Characterization of Coated Drug-Eluting Vascular Stent Systems

CDT-5 Coating Durability Tester

CDT-20 Coating Durability Tester

APT Acute Particulate Tester

ASTM F3036-13

Standard Guide for Testing Absorbable Stents

SVP-24 Stent Tester

UST Stent Tester

CDT-5 Coating Durability Tester

CDT-20 Coating Durability Tester

APT Acute Particulate Tester

ASTM WK46148

New Guide for Coating Characterization of Drug-Coated Balloons

APT Acute Particulate Tester

ASTM WK60510

New Test Method for Simulated use testing of neurointerventional device in tortuous vasculature

APT Acute Particulate Tester

ASTM WK60511

New Test Method for Particle evaluation and characterization for neurointerventional devices

APT Acute Particulate Tester

M6 Heart Valve Tester		ISO 5840-1:2015 ISO 5840-2:2015	ISO 5840-3:2013 ISO 12417-1:2015	
MP3 Pulse Duplicator		ISO 5840-1:2015 ISO 5840-2:2015	ISO 5840-3:2013	
DCT Compliance Tester		ISO 7198:2016		
SVP-24 Stent Tester	ISO 7198:2016 ISO 12417-1:2015	ISO/TS 17137:2014 ISO 25539-1:2017	ISO 25539-2:2012 ASTM F2477-07	ASTM F3036-13
UST Stent Tester	ISO 7198:2016 ISO 12417-1:2015	ISO/TS 17137:2014 ISO 25539-1:2017	ISO 25539-2:2012 ASTM F2477-07	ASTM F3036-13
CDT-5 Coating Durability Tester		ISO 12417-1:2015 ISO/TS 17137:2014	ISO 25539-2:2012 ASTM F2477-07	ASTM F2743-11 ASTM F3036-13
CDT-20 Coating Durability Tester		ISO 12417-1:2015 ISO/TS 17137:2014	ISO 25539-2:2012 ASTM F2477-07	ASTM F2743-11 ASTM F3036-13
APT Acute Particulate Tester		ISO 12417-1:2015 ISO/TS 17137:2014 ISO 25539-2:2012	AAMI TIR42:2010 ASTM F2394-07(2017) ASTM F2743-11	ASTM F3036-13 ASTM WK46148 ASTM WK60510 ASTM WK60511
PVAD Pulsatile VAD Tester		ISO 14708-5:2010		

Dynatek's products are designed to fulfill current and anticipated international regulations.

To receive a customized proposal, contact us today at:

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