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SYNOPSIS

Doc: MHD 06 (13124) IS/ISO 12417-1:2015 Cardiovascular implants and extracorporeal systems — Vascular Device-drug combination products —Part 1: General requirements

Scope:

This part of Indian Standard specifies requirements for vascular device-drug combination products (VDDCPs) based upon current technical and medical knowledge. VDDCPs are medical devices with various clinical indications for use in the human vascular blood system. A VDDCP incorporates, as an integral part, substance(s) which, if used separately, can be considered to be a medicinal substance or product (drug substance, drug product) but the action of the medicinal substance is ancillary to that of the device and supports the primary mode of action (PMOA) of the device. With regard to safety, this standard outlines requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer.

Salient features of content:

This part of Indian Standard is not comprehensive with respect to the pharmacological evaluation of VDDCPs. Absorbable components of VDDCPs (e.g. coatings) are addressed by this part of Indian Standard in their connection with drug-related aspects of the device. Degradation and other time-dependent aspects of absorbable implants and coatings are not completely addressed. This Standard does not address issues associated with viable or non-viable biological materials such as tissues, cells, or proteins. It also does not address issues associated with active surgical implants (i.e. implants that require power not generated by the human body or gravity).

c) Type/grades/classes, if any covered in the standard: Nil.
