

## SYNOPSIS

**Doc: MHD 07 (13742) IS/ISO 17327-1:2018 - Non-active surgical implants — Implant coating — Part 1: General requirements.**

### **Scope:**

This document specifies general requirements for implant coatings, comprising both surface coatings and surface modifications, applied to non-active surgical implants. This document specifies requirements concerned with generic coating properties including chemical and phase compositions, surface texture, coating coverage integrity, dissolvability, coating thickness, adhesion strength, abrasion resistance, porosity and pore size, and surface wettability.

This document is applicable to surface coatings, which are defined as layers of material with any different property than the natural surface of the substrate which are intentionally added to the substrate.

This document is applicable to surface modifications, which are defined as intentional conversion or reconstruction of the surface of the original substrate to form a new surface material consisting of components of the substrate's own material and possibly foreign material and forming a surface layer with different properties.

Since the pertinent properties of a coating and their needed level of characterization are highly dependent on the intended application of the implant, the generic nature of the general requirements in this document is not intended to either override or replace the provisions of application-specific performance standards.

### **a) Salient features of content:**

This document is not applicable to surfaces modified by texturing with the exclusive intention to change the roughness of the surface or the strength of the raw material.

This document is not applicable to natively passivated metal surfaces. While this document is applicable to intentionally passivated metal surfaces, well-established materials passivated by conventional techniques, such as nitric acid immersion, are usually non-hazardous and can be described in a very basic manner.

This document is not applicable to implant coatings utilizing viable tissue.

This document is not applicable to laminates, i.e. composite materials made of multiple layers, e.g. vascular prosthesis constructed of different expanded polytetrafluoroethylene layers, except the exposed surface of the laminate, which can be an implant coating.

This document is not applicable to coverings, e.g. covered stents

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

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