



Medical Device Definition

To serve as guidance for Regulatory Authorities, Conformity Assessment Bodies and the regulated Industry, the Global Harmonization Task Force – GHTF developed the document “Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’”.¹

‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

‘In Vitro Diagnostic (IVD) medical device’ means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

¹ GHTF/SG1/N071:2012 and referred to by the IMDRF in IMDRF/SAMD WG/N10final:2013.