ISO 13485, Clause 3 Terms and definitions

The following definitions should be regarded as generic, as definitions provided in national regulations can differ slightly and take precedence.

3.1
active implantable medical device
active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

3.2
active medical device
medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.3
advisory notice
notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in

- the use of a medical device,
- the modification of a medical device,
- the return of the medical device to the organization that supplied it, or
- the destruction of a medical device

NOTE Issue of an advisory notice might be required to comply with national or regional regulations.

3.4
customer complaint
written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market

3.5
implantable medical device
medical device intended

- to be totally or partially introduced into the human body or a natural orifice, or
- to replace an epithelial surface or the surface of the eye,

by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention
NOTE This definition applies to implantable medical devices other than active implantable medical devices.

3.6
labelling

written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or
- accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents

NOTE Some regional and national regulations refer to “labelling” as “information supplied by the manufacturer.”

3.7
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, 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 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 for medical purposes by means of in vitro examination of specimens derived from the human body,

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

NOTE This definition has been developed by the Global Harmonization Task Force (GHTF). See bibliographic
reference [15].

3.8
sterile medical device
category of medical device intended to meet the requirements for sterility

NOTE The requirements for sterility of a medical device might be subject to national or regional regulations or
standards.