Note 2 to entry: *Accompanying documentation* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types.

3.2
benefit
positive impact or desirable outcome of the use of a *medical device* (3.10) on the health of an individual, or a positive impact on patient management or public health

Note 1 to entry: *Benefits* can include positive impact on clinical outcome, the patient's quality of life, outcomes related to diagnosis, positive impact from diagnostic devices on clinical outcomes, or positive impact on public health.

3.3
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 63:2019, 3.1]

3.4
hazard
potential source of *harm* (3.3)

[SOURCE: ISO/IEC Guide 63:2019, 3.2]

3.5
hazardous situation
circumstance in which people, property or the environment is/are exposed to one or more *hazards* (3.4)

Note 1 to entry: See Annex C for an explanation of the relationship between hazard and hazardous situation.

[SOURCE: ISO/IEC Guide 63:2019, 3.3, modified — Note 1 to entry added.]

3.6
intended use
intended purpose
use for which a product, *process* (3.14) or service is intended according to the specifications, instructions and information provided by the *manufacturer* (3.9)

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the *intended use*.

[SOURCE: ISO/IEC Guide 63:2019, 3.4]

3.7
in vitro diagnostic medical device
IVD medical device
device, whether used alone or in combination, intended by the *manufacturer* (3.9) for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

[SOURCE: ISO 18113-1:2009, 3.27, modified — NOTE deleted.]

3.8
life cycle
series of all phases in the life of a *medical device* (3.10), from the initial conception to final decommissioning and disposal

[SOURCE: ISO/IEC Guide 63:2019, 3.5]

3.9
manufacturer
natural or legal person with responsibility for the design and/or manufacture of a *medical device* (3.10) with the intention of making the *medical device* (3.10) available for use, under his name, whether or not such a *medical device* (3.10) is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: The natural or legal person has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the *medical device* in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The *manufacturer's* responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture" may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a *medical device*; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a *medical device* that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the *manufacturer*, provided the assembly or adaptation does not change the *intended use* of the *medical device*.

Note 5 to entry: Any person who changes the *intended use* of, or modifies, a *medical device* without acting on behalf of the original *manufacturer* and who makes it available for use under his own name, should be considered the *manufacturer* of the modified *medical device*.

Note 6 to entry: An authorised representative, distributor or importer who only adds its own address and contact details to the *medical device* or the packaging, without covering or changing the existing labelling, is not considered a *manufacturer*.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a *medical device*, the person responsible for the design and/or manufacture of that accessory is considered to be a *manufacturer*.

[SOURCE: ISO/IEC Guide 63:2019, 3.6]

3.10
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* (3.9) 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* (3.10),

— providing information by means of in vitro examination of specimens derived from the human body,

and which 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 function by such means

Note 1 to entry: Products which can be considered to be *medical devices* in some jurisdictions but not in others include:

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO/IEC Guide 63:2019, 3.7]

3.11
objective evidence
data supporting the existence or verity of something

Note 1 to entry: *Objective evidence* can be obtained through observation, measurement, test or by other means.

[SOURCE: ISO 9000:2015, 3.8.3, modified — Note 2 to entry deleted.]

3.12
post-production
part of the *life cycle* (3.8) of the *medical device* (3.10) after the design has been completed and the *medical device* (3.10) has been manufactured

EXAMPLE Transportation, storage, installation, product use, maintenance, repair, product changes, decommissioning and disposal.

3.13
procedure
specified way to carry out an activity or a *process* (3.14)

Note 1 to entry: *Procedures* can be documented or not.

[SOURCE: ISO 9000:2015, 3.4.5]

3.14
process
set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the "intended result" of a *process* is called output, product or service depends on the context of the reference.

Note 2 to entry: Inputs to a *process* are generally the outputs of other *processes* and outputs of a *process* are generally the inputs to other *processes*.

Note 3 to entry: Two or more interrelated and interacting *processes* in series can also be referred to as a *process*.

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes to entry 4, 5 and 6 are deleted.]

3.15
reasonably foreseeable misuse
use of a product or system in a way not intended by the *manufacturer* (3.9), but which can result from readily predictable human behaviour

Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. lay and professional users.

Note 2 to entry: *Reasonably foreseeable misuse* can be intentional or unintentional.

[SOURCE: ISO/IEC Guide 63:2019, 3.8]

3.16
record
document stating results achieved or providing evidence of activities performed

Note 1 to entry: *Records* can be used, for example, to formalize traceability and to provide evidence of *verification*, preventive action and corrective action.

Note 2 to entry: Generally *records* need not be under revision control.

[SOURCE: ISO 9000:2015, 3.8.10]

3.17
residual risk
risk remaining after *risk control* (3.21) measures have been implemented

[SOURCE: ISO/IEC Guide 63:2019, 3.9]

3.18
risk
combination of the probability of occurrence of *harm* (3.3) and the *severity* (3.27) of that *harm* (3.3)

[SOURCE: ISO/IEC Guide 63:2019, 3.10, modified — Note 1 to entry deleted.]

3.19
risk analysis
systematic use of available information to identify *hazards* (3.4) and to estimate the *risk* (3.18)

[SOURCE: ISO/IEC Guide 63:2019, 3.11]

3.20
risk assessment
overall *process* (3.14) comprising a *risk analysis* (3.19) and a *risk evaluation* (3.20)

[SOURCE: ISO/IEC Guide 51:2014, 3.11]

3.21
risk control
process (3.14) in which decisions are made and measures implemented by which *risks* (3.18) are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:2019, 3.12]

3.22
risk estimation
process (3.14) used to assign values to the probability of occurrence of *harm* (3.3) and the *severity* (3.27) of that harm

[SOURCE: ISO/IEC Guide 63:2019, 3.13]

3.23
risk evaluation
process (3.14) of comparing the estimated *risk* (3.18) against given *risk* (3.18) criteria to determine the acceptability of the *risk* (3.18)

[SOURCE: ISO/IEC Guide 63:2019, 3.14]

3.24
risk management
systematic application of management policies, *procedures* (3.13) and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.18)

[SOURCE: ISO/IEC Guide 63:2019, 3.15]

3.25
risk management file
set of *records* (3.16) and other documents that are produced by *risk management* (3.24)

3.26
safety
freedom from *unacceptable risk* (3.18)

[SOURCE: ISO/IEC Guide 63:2019, 3.10]

3.27
severity
measure of the possible consequences of a *hazard* (3.4)

[SOURCE: ISO/IEC Guide 63:2019, 3.17]

3.28
state of the art
developed stage of technical capability at a given time as regards products, *processes* (3.14) and services, based on the relevant consolidated findings of science, technology and experience

Note 1 to entry: The *state of the art* embodies what is currently and generally accepted as good practice in technology and medicine. The *state of the art* does not necessarily imply the most technologically advanced solution. The *state of the art* described here is sometimes referred to as the "generally acknowledged *state of the art*".

[SOURCE: ISO/IEC Guide 63:2019, 3.18]

3.29
top management
person or group of people who directs and controls a *manufacturer* (3.9) at the highest level

[SOURCE: ISO 9000:2015, 3.1.1, modified — "An organization" replaced by "a *manufacturer*", Notes to entry deleted.]

3.30
use error
user action or lack of user action while using the *medical device* (3.10) that leads to a different result than that intended by the *manufacturer* (3.9) or expected by the user

Note 1 to entry: *Use error* includes the inability of the user to complete a task.

Note 2 to entry: *Use errors* can result from a mismatch between the characteristics of the user, user interface, task, or use environment.

Note 3 to entry: Users might be aware or unaware that a *use error* has occurred.

Note 4 to entry: An unexpected physiological response of the patient is not by itself considered *use error*.

Note 5 to entry: A malfunction of a *medical device* that causes an unexpected result is not considered a *use error*.

[SOURCE: IEC 62366-1:2015, 3.21, modified — Note 6 to entry deleted.]

3.31
verification
confirmation, through the provision of *objective evidence* (3.11), that specified requirements have been fulfilled

Note 1 to entry: The *objective evidence* needed for a *verification* can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The activities carried out for *verification* are sometimes called a qualification *process*.

Note 3 to entry: The word "verified" is used to designate the corresponding status.