Standards definitions

Definitions of some terms given in the standards

# EU Regulation 2017/745

### Medical device

‘Medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

* diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
* diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
* investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
* providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal 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.

The following products shall also be deemed to be medical devices:

* devices for the control or support of conception;
* products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

### Accessory for a medical device

‘Accessory for a medical device’ means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).

### Custom-made device

‘Custom-made device’ means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices.

### Active device

‘Active device’ means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.

Software shall also be deemed to be an active device.

### Implantable device

‘Implantable device’ means any device, including those that are partially or wholly absorbed, which is intended:

* to be totally introduced into the human body, or
* to replace an epithelial surface or the surface of the eye,

by clinical intervention and which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.

### Invasive device

‘Invasive device’ means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

### Single-use device

‘Single-use device’ means a device that is intended to be used on one individual during a single procedure.

### Intended purpose

‘Intended purpose’ means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.

### Label

‘Label’ means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.

### Instructions for use

‘Instructions for use’ means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.

### Performance

‘Performance’ means the ability of a device to achieve its intended purpose as stated by the manufacturer.

### Risk

‘Risk’ means the combination of the probability of occurrence of harm and the severity of that harm.

### User

‘User’ means any healthcare professional or lay person who uses a device.

### Lay person

‘Lay person’ means an individual who does not have formal education in a relevant field of healthcare or medical discipline.

### Clinical evaluation

‘Clinical evaluation’ means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.

### Clinical investigation

‘Clinical investigation’ means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device.

### Investigational device

‘Investigational device’ means a device that is assessed in a clinical investigation.

### Clinical investigation plan

‘Clinical investigation plan’ means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation.

### Clinical data

‘Clinical data’ means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

* clinical investigation(s) of the device concerned,
* clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,
* reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,
* clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up.

### Subject

‘Subject’ means an individual who participates in a clinical investigation.

### Clinical evidence

‘Clinical evidence’ means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer.

### Clinical performance

‘Clinical performance’ means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer.

### Clinical benefit

‘Clinical benefit’ means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.

### Investigator

‘Investigator’ means an individual responsible for the conduct of a clinical investigation at a clinical investigation site.

### Informed consent

‘Informed consent’ means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation.

### Adverse event

‘Adverse event’ means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device.

### Serious adverse event

‘Serious adverse event’ means any adverse event that led to any of the following:

1. death,
2. serious deterioration in the health of the subject, that resulted in any of the following:
   1. life-threatening illness or injury,
   2. permanent impairment of a body structure or a body function,
   3. hospitalisation or prolongation of patient hospitalisation,
   4. medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
   5. chronic disease,
3. foetal distress, foetal death or a congenital physical or mental impairment or birth defect.

### Device deficiency

‘Device deficiency’ means any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer.

### Withdrawal

‘Withdrawal’ means any measure aimed at preventing a device in the supply chain from being further made available on the market.

### Incident

‘Incident’ means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

### Serious incident

‘Serious incident’ means any incident that directly or indirectly led, might have led or might lead to any of the following:

1. the death of a patient, user or other person,
2. the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
3. a serious public health threat.

# IEC 62366-1

### Abnormal use

Conscious, intentional act or intentional omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer.

### Accompanying documentation

Materials accompanying a medical device and containing information for the user or those accountable for the installation, use and maintenance of the medical device, particularly regarding safe use.

### Correct use

Normal use without use error.

### Formative evaluation

User interface evaluation conducted with the intent to explore user interface design strengths, weaknesses, and unanticipated user errors.

### Hazard-related use scenario

Use scenario that could lead to a hazardous situation or harm.

### Normal use

Operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those medical devices provided without instructions for use.

### Patient

Living being (person) undergoing a medical, surgical or dental procedure.

### Primary operating function

Function that involves user interaction that is related to the safety of the medical device.

### Summative evaluation

User interface evaluation conducted at the end of the user interface development with the intent to obtain objective evidence that the user interface can be used safely.

### Task

One or more user interactions with a medical device to achieve a desired result.

### Usability

Characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction in the intended use environment.

### Usability engineering

Application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of medical devices (including software), systems and tasks to achieve adequate usability.

### Use environment

Actual conditions and setting in which users interact with the medical device.

### Use error

User action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user.

### Use scenario

Specific sequence of tasks performed by a specific user in a specific use environment and any resulting response of the medical device.

### Use specification

Summary of the important characteristics related to the context of use of the medical device.

### User

Person interacting with (i.e. operating or handling) the medical device.

### User group

Subset of intended users who are differentiated from other intended users by factors that are likely to influence usability, such as age, culture, expertise or type of interaction with a medical device.

### User interface

Means by which the user and the medical device interact.

### User interface specification

Collection of specifications that comprehensively and prospectively describe the user interface of a medical device.

# FDA Guidance

### Abnormal use

An intentional act or intentional omission of an act that reflects violative or reckless use or sabotage beyond reasonable means of risk mitigation or control through design of the user interface.

### Critical task

A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care.

### Formative evaluation

Process of assessing, at one or more stages during the device development process, a user interface or user interactions with the user interface to identify the interface’s strengths and weaknesses and to identify potential use errors that would or could result in harm to the patient or user.

### Hazard

Potential source of harm.

### Hazardous situation

Circumstance in which people are exposed to one or more hazard(s).

### Human factors engineering

The application of knowledge about human behavior, abilities, limitations, and other characteristics of medical device users to the design of medical devices including mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safe and effective use.

Human factors engineering and usability engineering can be considered to be synonymous.

### Human factors validation testing

Testing conducted at the end of the device development process to assess user interactions with a device user interface to identify use errors that would or could result in serious harm to the patient or user. Human factors validation testing is also used to assess the effectiveness of risk management measures. Human factors validation testing represents one portion of design validation.

### Task

Action or set of actions performed by a user to achieve a specific goal.

### Use error

User action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user and (2) was not caused solely by device failure and (3) did or could result in harm. Use safety Freedom from unacceptable use-related risk.

### User

Person who interacts with (i.e., operates or handles) the device.

### User interface

All points of interaction between the user and the device, including all elements of the device with which the user interacts (i.e., those parts of the device that users see, hear, touch). All sources of information transmitted by the device (including packaging, labeling), training and all physical controls and display elements (including alarms and the logic of operation of each device component and of the user interface system as a whole).

# References

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
2. IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. Edition 1.0. Geneva: International Electrotechnical Commission; 2015. ISBN:978-2-8322-2281-2.
3. FDA (2016) Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff.