Version 1
2026-03

Data Element Detailed Description for DIN SPEC 91509:2026-03 Release #1

Contents

1 General Information

1.1 Purpose & Scope

This document provides a comprehensive description of the details associated with each data model element defined in the context of DIN SPEC 91509. **It serves as a supporting reference** to improve the readability, interpretability, and consistent application of the underlying data model. Consider DIN SPEC 91509 as the main document to be compliant.

Specifically, this document includes all data model elements that are part of Data Model Release #1, as defined in the accompanying XML Schema (XSD). For each element, key metadata such as identification, description, attributes, application guidance, regulatory context, and limitations are systematically documented.

The content is intended to support developers, implementers, and regulatory stakeholders in understanding and applying the data model in a consistent and transparent manner.

1.2 Provided information

Single elements of the data model are named "Knowledge Topics", short form "KT". Each KT is provided with the below listed information (= KT content).

Public ID
Each data model element is uniquely identified by a Public ID. This identifier ensures unambiguous reference and traceability throughout the data model.

Title
The Title denotes the name of the respective Knowledge Topic (KT). It serves as the primary label for the element and facilitates quick recognition and referencing.

Description
The Description provides a concise explanation of the meaning and intended use of the Knowledge Topic. It supports the correct interpretation and application within the broader context of the data model.

Attributes
Attributes are listed optionally for each Knowledge Topic to describe characteristics that are inherently linked to the KT in a one-to-one relationship. These attributes cannot be separated from the KT without losing semantic integrity.

Information for KT Application
This section contains specific information regarding the usage of the Knowledge Topic within the technical documentation. It focuses on KT-specific implementation aspects and does not include general procedural instructions such as the generation of multiple knowledge units per KT or the structuring of sub-KTs.

Binding Force
The Binding Force indicates the normative character of the Knowledge Topic. It specifies whether the KT is required by legislation, standards, or guidance documents, or if its application is based on established best practices.

Limitations
This section identifies any known constraints regarding the applicability of the Knowledge Topic. It highlights contexts or device types for which the KT may not be relevant or suitable.

Description of Limitations
Where limitations exist, this section provides a detailed description. It explains the nature and rationale of the constraints, for example, if a particular KT is only relevant for devices with a defined medical purpose.

Source of KT Definition
The source section documents the origin of the Knowledge Topic definition. This may include references to legislation, standards, or guidance documents. If a KT is defined based on multiple sources, a specific definition developed within the MDKU context is provided.

Justification of KT Definition
This section outlines the rationale behind the selected KT definition. It explains the reasoning for the chosen formulation and, where applicable, the distinction from similar or related KTs.

Existing Regulatory Definitions
An overview of existing definitions from relevant regulatory frameworks is provided to support harmonization and traceability. This enables users to compare the KT with established definitions in applicable legal or normative texts.

1.3 Structure

In this document the following structure applies for each KT:

— Heading;

— Public ID – Title;

— Description;

— Attributes;

— Information for KT Application;

— Binding Force;

— Limitations;

— Description of Limitations;

— Source of KT Definition;

— Justification of KT Definition;

— Existing Regulatory Definitions.

2 Content of the Release

2.1 Technical Documentation

2.1.1 Intended Purpose/Intended Use

10 - Intended Purpose/Intended Use

The intended purpose/intended use consists of information that describe the use for which a device is intended according to the data supplied by the manufacturer in the technical documentation.

KT Attributes	NA
Information for KT Application	**Intended Purpose vs. Intended Use** Current situation in Europe: • Both terms appear to be part of everyday language in the industry and documentation for medical devices. • Only Intended Purpose is defined in the European Medical Device Regulation, but both terms are used in the law: Intended Purpose 87x, Intended Use 16x. • There is no clear definition, which detailed information belongs to the Intended Purpose and/or Intended Use. • Both terms are used in some European MDCG guidelines in a slightly different way. Both terms are used very vaguely and contain - if at all mentioned in guidelines - only examples of associated detailed information, but not a comprehensive overview. • In the international context, many standards with relevance for the medical device industry use the same definition for intended purpose and intended use (e.g. ISO 14971 and at least 15 other standards). Their definition is based on the definition for "Intended use" as defined in ISO/IEC Guide 63:2019, 3.4. - Guide to the development and inclusion of aspects of safety in International Standards for medical devices. This guide lists typical elements of the intended use, such the intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle. Based on this situation, the data model does not differentiate between Intended Purpose/Intended Use in order to provide sufficient flexibility. **Use of the KT within a company:** If a company wants to differentiate between these two terms, the data model can be extended with additional company specific KTs in which the separate definitions for Intended Purpose and Intended Use can be defined. In that case, that separate KTs (each for Intended Purpose and Intended Use) have a child - parent relatationship with the higher-level generic KT Intended Purpose/Intended Use that is part of the released public data model. **Intended Purpose/Intended Use Lifecycle** Information related to the intended purpose/intended use evolves over the complete product lifecycle and is not entirely static. For example,

	typically information such as the medical purpose, indication and patient population are defined as input for product development. Later, during the development phase, information about contra-indications, warnings are added. And as results of post-market surveillance activities, the need for changes of intended purpose/intended use information may arise.
Binding Force of KT Title	Regulatory - Mandatory
Limitations	No
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	Currently, we have an unclear regulatory situation in Europe: • Both terms appear to be part of everyday language in the industry and documentation for medical devices. • Only Intended Purpose is defined in the European Medical Device Regulation, but both terms are used in the law: Intended Purpose 87x, Intended Use 16x. • There is no clear definition, which detailed information belongs to the Intended Purpose and/or Intended Use. • Both terms are used in some European MDCG guidelines in a slightly different way. Both terms are used very vaguely and contain - if at all mentioned in guidelines - only examples of associated detailed information, but not a comprehensive overview. • In the international context, many standards with relevance for the medical device industry use the same definition for intended purpose and intended use (e.g. ISO 14971 and at least 15 other standards). Their definition is based on the definition for "Intended use" as defined in ISO/IEC Guide 63:2019, 3.4. - Guide to the development and inclusion of aspects of safety in International Standards for medical devices. This guide lists typical elements of the intended use, such the intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle. Based on those facts, we decided that the data model shall not differentiate between Intended Purpose/Intended Use in order to provide sufficient flexibility. The existing definition in the MDR is not clear enough from our point of view: it only provides information about a few elements of the technical documentation in which information about intended purpose can be found. This list is not comprehensive. Furthermore, the MDR definition does not consider and provide additional Information related to the product lifecycle of a medical device.
Existing regulatory definitions	<u>Existing definitions related to the Intended Purpose:</u> **MDR Article 2:** Definitions (12): ‘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; (ID-3087) --- **MDCG 2020-6, 1.2 Additional terms not defined in MDR Article 2** [Indications] should be distinguished from '**intended purpose/intended use', which describes the effect of a device**. --- **ISO 14971:2019 (ISO/IEC Guide 63:2019,3.4):** 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. --- ADDITIONAL INFORMATION related to the use of the term "Intended Purpose" **IEC 62366-1:2015+AMD1:2020, section 5.1:** The MANUFACTURER shall prepare a USE SPECIFICATION. The USE SPECIFICATION shall include: • *intended medical indication; NOTE 1 This can include conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented. • intended PATIENT population; NOTE 2 This can include age group, weight range, health, or condition. • intended part of the body or type of tissue applied to or interacted with; • intended USER PROFILE; • intended USE ENVIRONMENT; and • operating principle. NOTE 3 The summary of the MEDICAL DEVICE USE SPECIFICATION is referred to by some authorities having jurisdiction as the 'statement of intended use'. --- **IEC 62366-1:2015+AMD1:2020, section 3.23:** Use Specification (Application Specification): Summary of the important characteristics related to the context of use of the MEDICAL DEVICE 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 USE SPECIFICATION. Note 2 to entry: The summary of the MEDICAL DEVICE USE SPECIFICATION is referred to by some authorities having jurisdiction as the 'statement of intended use'. Note 3 to entry: The USE SPECIFICATION is an input to determining the INTENDED USE of ISO 14971:2007. ---

	MEDDEV 2.7.1 rev. 4, A3. Device description - typical contents - intended purpose of the device - exact medical indications (if applicable) - name of disease or condition/ clinical form, stage, severity/ symptoms or aspects to be treated, managed or diagnosed - patient populations (adults / children / infants, other aspects) - intended user (use by health care professional / lay person) - organs / parts of the body / tissues or body fluids contacted by the device - duration of use or contact with the body - repeat applications, including any restrictions as to the number or duration of re applications - contact with mucosal membranes/ invasiveness/ implantation - contraindications - precautions required by the manufacturer - single use / reusable - other aspects --- **MDCG 2020-6: Appendix II** – Clinical Evaluation Plan for Legacy Devices A modified Clinical Evaluation Plan for legacy devices should include at least: • An identification of the GSPR that require support from relevant clinical data. • A specification of the intended purpose of the device. • A clear specification of intended target groups with clear indications and contra indications. -> intended purpose, intended target populations, indications contraindications, etc. are treated as separate contents in the MDR, i.e. intended purpose not a over-term for many sub-terms! The intended purpose is usually a short statement of two or three sentences that focuses on what the device is intended to be used for. It is a required item in the Technical Documentation (Annex II, 1.1) https://eumdr.com/intended-purpose/ --- **MDCG 2022- 2021 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR)** ACCORDING TO REGULATION (EU) 2017/745 (MDR), December 2022, Annnex I under Description of the devices: "The intended purpose of the device(s) as per the Instructions for Use according to Annex I, Chapter III, 23.4(b) MDR, any indications, contra-indications, and target populations."

2.1.2 Intended Purpose/Intended Use Statement

20 - Intended Purpose/Intended Use Statement

The intended purpose/intended use statement is a short version of the intended purpose/intended use.

KT Attributes	NA

Information for KT Application	**Intention of the KT:**
	The intended purpose/intended use statement is used whenever a short version of the comprehensive intended purpose/intended use description is needed, e.g. for product certificates, Eudamed, or different documents of the technical documentation/different processes that ask for the intended purpose.
	Proposed structure:
	"The device (XYZ) is a (DEVICE TYPE) used for (FUNCTION) in (APPLICATION TARGET/LOCATION)."
	Industry examples:
	They shall help to understand, which content is typically used for certificates/is expected by Notified Bodies:
	• The device is
	  • is used for cutting of tissue
	  • intended to support minimal invasive surgery by illuminating the OP site
	  • a solution for irrigation
	  • a fully implantable port-catheter system for venous vascular access.
	  • intended to administer investigational drug products as an aerosol for inhalation in a ventilator circuit in clinical trials.
	  • used for the customized fabrication of primary screw-retained or cemented prosthesis.
	  • Imaging and observation of the cellular layers of the anterior segment of the human eye, for the diagnosis and management of anterior segment diseases.
	  • intended for stable anchoring of total or partial joint endoprostheses in living bone
	  • intended for non-invasive treatment of axillary hyperhidrosis
	  • is designed to provide therapeutic techniques and exercises based on evidence-based psychological-psychotherapeutic treatment approaches that are appropriate for patients with multiple sclerosis (MS) or clinically isolated syndrome (CIS) to support them in managing their MS or CIS.
	• Device group abc
	  • consists of instruments to used in connection with devices xyz and the defined application of those devices.

Binding Force of KT Title	Best Practice

Limitations	No
Description of known Limitations	
Source of KT Definition	MDKU Specific
Justification of KT Definition	The MDR requires in Annex XII, Chapter 1, 4. (a) that the intended purpose shall be documented on certificates. According to MDR, Article 2 (12), the intended purpose is a term that includes a hughe variety of information, that cannot be documented on a certificate. Practically, only a short form of the intended purpose can be documented on the certificate. It is therefore mandatory to clearly differentiate between the comprehensive intended purpose (including all details) and the short version, for which we introducted the term "intended purpose statement". Currently it is not clear in the MDR, when/where the comprehensive intended purpose and when/where the intended purpose statement is required. The same problem occurs on the Eudamed website (intended purpose field has limited number of characters, and the Clinical Evaluation Assessment Report (CEAR) Template for Notified Bodies (see MDCG 2020-13). For the last two, we recommend the use of the "intended purpose statement". Furthermore, "intended purpose" information is required on the label (MDR, Annex I, 23.2 (b)), marketing material, instructions for use - here it is not clear again, if the comprehensive or short version is required.
Existing regulatory definitions	There is no regulatory document that uses a term that we can consider a "short version" of the intended purpose/intended use. Different regulatory documents use the terms "intended purpose", "intended use", with partly different interpretations, which single information items are included. See also information provided for the 1 ID-2663 - Intended Purpose/Intended Use.

2.1.3 Medical Device Accessory

30 - Medical Device Accessory

Medical device accessory 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 to be used in accordance with its intended purpose,

— or to specifically and directly assist the medical functionality of the medical device in terms of its intended purpose

KT Attributes	
Information for KT Application	
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Yes (See description of know limitations)
Description of known Limitations	Not all medical device have one or more accessories, there are medical devices that function without accessories.
Source of KT Definition	Legislation
Justification of KT Definition	The description of the KT is based on the definition for accessory for a medical device in MDR, Article 2.
Existing regulatory definitions	MDR, Article 2, (2) ‘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);

2.1.4 Compatible Devices

40 - Compatible Device(s)

A compatible device, including software, is a device that is used together with one or more medical devices in accordance with their intended purpose, to:

a) perform without losing or compromising the ability to perform as intended, and/or

b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or

c) be used together without conflict/interference or adverse reaction

KT Attributes	
Information for KT Application	It might be differentiated between the following types of compatibility: • **Open compatibility:** all other devices that match the interaction specification of the particular medical device • **Closed compatibility:** a specified list of devices that can interact with the particular medical device, for which the compatibility has been verified and validated. Possible interactions: electrical, chemical, physical, biological, digital
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Yes (See description of know limitations)
Description of known Limitations	Not all devices have a compatibility with other devices.
Source of KT Definition	Legislation
Justification of KT Definition	The description of the KT is based on the definition for compatibility in MDR, Article 2. When two devices shall be used in combination with each other, it is mandatory that they are compatible. The differentiation of compatibility types is not consistently mentioned in regulatory documents but is used in various ways in the industry. The scope of the definition is focused on a device that is used in combination with a medical device.
Existing regulatory definitions	1. MDR, Article 2: Definitions For the purposes of this Regulation, the following definitions apply: (1) '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, 2. MDR, Article 2, (25) ‘compatibility’ is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose, to: • (a) perform without losing or compromising the ability to perform as intended, and/or • (b) integrate and/or operate without the need for modification or adaption of any part of the combined devices, and/or • (c) be used together without conflict/interference or adverse reactio

2.2 Product Development

2.2.1 Mode of Action

50 - Mode of Action

The mode of action is a detailed description how the medical device accomplishes its intended purpose or generates its desired effect. Is used synonymously with the term "principle mode of action".

KT Attributes	"**Principal** mode of action" = a systematic description of the mode of action, which in turn must be presented in much greater detail as the "mode of action" description.
Information for KT Application	
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Yes (See description of know limitations)
Description of known Limitations	Not all products have a “Mode of action”, example are glases. It is proposed that the term is used for combination devices only.
Source of KT Definition	MDKU Specific
Justification of KT Definition	The term is not defined in the MDR. We see the "Principal mode of action" as an attribute of the "Mode of action"; the former is a systematic description of the mode of action, which in turn must be presented in much greater detail.
Existing regulatory definitions	MDR Article 1 section 6 b) MDCG 2022 - 5 Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices: 1.2.2 Definitions of pharmacological, immunological, metabolic means 3. ‘**Principal mode of action**’ (*referred to in Article 1(6)(b) MDR*), (page 6.) "The principal mode of action represents the means by which the product achieves its principal intended action, i.e. pharmacological, immunological, metabolic, physical or other. It is objective and must be based on state of the art scientific data." FDA: Definition of Primary Mode of Action of a Combination Product Federal Register :: Definition of Primary Mode of Action of a Combination Product Mode of action would be defined as “the means by which a product achieves a therapeutic effect.” For purposes of this definition, “therapeutic” effect or action includes any effect or action of the combination product intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body. Products may have a drug, biological product, or device mode of action. Because combination products are comprised of more than one type of regulated article (biological product, device, or drug), and each constituent part contributes a biological product, device, or drug mode of action, combination products will typically have more than one mode of action.

2.2.2 Operating principle

60 - Operating principle

The operating principle for a medical device includes descriptions of:

— methods used to accomplish its intended purpose; and

— mechanisms by which it works

KT Attributes	NA
Information for KT Application	The operating principle for a medical device includes descriptions of the means by which a device works and brings about its intended effect. The term "Principle of Device Operation" is understood as identical with the term "Operating Principle".
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	--
Justification of KT Definition	**MDR Annex II 1.1. d)** (d) principles of operation of the device and its mode of action, scientifically demonstrated if necessary
Existing regulatory definitions	IEC 62366-1:2015+AMD1:2020 ANNEX A.2 Subclause 5.1 (operating principle), Prepare Use specification, page 35 The operating principle for a MEDICAL DEVICE includes descriptions of: – physical methods used to accomplish its INTENDED USE; and EXAMPLE 1 A scalpel using highly focused laser energy. EXAMPLE 2 A scalpel using sharpened stainless steel blade. EXAMPLE 3 A scalpel using high-energy HF electromagnetic fields. – mechanisms by which it works. EXAMPLE 4 An intravenous infusion pump delivers medication through an intravenous line connected to a PATIENT catheter by a peristaltic mechanism employing rollers and mechanical fingers that squeeze and push fluid through plastic tubing. EXAMPLE 5 An intravenous infusion pump delivers medication through an intravenous line connected to a PATIENT catheter by a volumetric pump that has plungers connected to a diaphragm on a cassette mechanism connected to PATIENT tubing that draws fluid from an IV bag by creating a vacuum within the cassette mechanism. Operating principle definition from a Canadian source: Operating principles are the means by which a device produces or brings about an intended or appropriate effect. They are the means whereby a device is able to have a certain influence on a person or its surroundings. Source: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-

	documents/guidance-document-interpretation-significant-change-medical-device.html#a262 - Section 1.4 Definitions NOTE: The Canadian source is not as strong as ISI 14971 and IEC 62366. Additionally, this is too complicated.

2.3 Risk Management

2.3.1 Information for Safety

70 - Information for Safety

Information for safety is a term that summaries different types of information provided to the user or responsible organization used as a risk control measure or disclosure of a residual risk.

KT Attributes	NA
Information for KT Application	• "Information for Safety" is an umbrella term that included different type of safety information such as warnings, precautions. • ISO/TR 24671, Annex D elaborates: “Information for safety is instructive and gives the user clear instructions of what actions to take or to avoid, in order to prevent a hazardous situation or harm from occurring.” It is therefore, a fitting KT in that it can include warnings, pre(cautions), disclosures of residual risk, instructions in the use of a medical device and explanations of a safety feature.”
Binding Force of KT Title	Best Practice
Limitations	No
Description of known Limitations	Not applicable.
Source of KT Definition	Guidance
Justification of KT Definition	Definition is identical with the IMDRF definition.
Existing regulatory definitions	**Input for KT definition:** IMDRF definition: “Information provided to the user or responsible organization that is used as a risk control measure or disclosure of a residual risk.

2.3.2 Precautions

80 - Precautions

Precautions are information regarding any special care users should exercise for the safe and effective use of the medical device, or to avoid damage to the medical device that could occur as a result of use, including misuse.

KT Attributes	NA
Information for KT Application	NA
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	Definition is based on information provided by IMDRF, see existing regulatory definitions.
Existing regulatory definitions	**Definition given in IMDRF** GRRP WG (PD1)/N52 Precaution: Information regarding any special care users should exercise for the safe and effective use of the device or IVD device, or to avoid damage to the device or IVD medical device that could occur as a result of use, including misuse (Adapted from ISO 18113-1). **Definition from ISO 18113-1** Vorsichtsmaßnahme Aussage, die die Anwender zu besonderer Sorgfalt oder zu besonderen Aktivitäten für die sichere und wirkungsvolle Anwendung eines In-vitro-Diagnostikums oder dazu aufruft, einen Schaden am In-vitro-Diagnostikum zu vermeiden, der als Folge der Anwendung, einschließlich Missbrauch entstehen könnte ANMERKUNG 1: Die Unterscheidung zwischen Warnhinweisen und Vorsichtsmaßnahmen ist eine Frage des Grades unter Berücksichtigung der Wahrscheinlichkeit und der Bedeutung der Gefahr. Siehe Definition Warnhinweis. ANMERKUNG 2: Angepasst aus Literaturhinweis (FDA, U.S. Food and Drug Administration, Guidance on Medical Device Patient Labelling; Final Guidance for Industry and FDA, 19. April 2001) **Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers, 2001** Appendix E, Warnings and precautions: What are warnings and precautions? The term **precaution** is used for the statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, ***may result in minor or moderate injury to the user or patient or damage to the equipment or other property***. [ANSI Z535.4-1998] It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse. ***The word CAUTION is generally used as the signal word for a precaution statement***.

	The distinction between warnings and precautions is a *matter of degree of likelihood and seriousness of the hazard*. The target audience for medical device labeling (health care practitioners and lay users of home use devices) generally recognize a hierarchy of hazard alerts, with warnings being those of a more serious nature and ***precautions being of a less serious, but important***, nature. existing guiding questions by the FDA in order to identify precautions: What is the purpose of warnings and precautions in medical device labeling? The basic purpose of a warning or precaution is twofold: · to inform users of potential personal and environmental hazards, and · to persuade them to modify their behavior to avoid injury or device damage. For a warning or precaution to be effective, readers must: · perceive the threat to be both severe and relevant to them, · believe that they can perform the recommended response, and · believe that response will be effective in avoiding the hazard. Effective warnings and precautions capture the reader's attention, are understood, are consistent enough with the reader's beliefs and attitudes to be accepted, and are persuasive enough to motivate the reader to comply. They invoke an appropriate level of fear arousal, conveying the nature and extent of the hazard, without being so strong that they backfire, causing the reader to select an alternative action or no action. **Definition from Device Labeling Guidance** #G91-1 (Blue Book Memo) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/device-labeling-guidance-g91-1-blue-book-memo) **Precautions** Include information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device, for example: - Indicate or emphasize any need for protective wear during use. - Identify any laboratory tests or other evaluations that may be helpful in following the patient's response or in identifying adverse reactions and, if appropriate, specify the frequency of such tests or evaluations before, during and after use of the device. The "Precautions" section of the labeling includes precautionary statements not appropriate for inclusion under other sections of the labeling. Additional guidance regarding precautions will be found in the "Special Patient Populations" section below.

2.3.3 Warnings

90 - Warnings

Warnings are information regarding any special care users should exercise for the safe and effective use of the medical device to avoid serious hazards or other serious unfavourable consequences that could occur as a result of the use ore misuse.

KT Attributes	NA
Information for KT Application	NA
Binding Force of KT Title	Regulatory - Mandatory
Limitations	No
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	NA
Existing regulatory definitions	Mentioned in • MDR • MDCG 2020-08 • MDCG 2019-09 • IMDRF GRRP WG (PD1)/N52 **--> Definition from IMDRF GRRP WG (PD1)/N52** Warning: Information describing a situation for which there is a foreseeable serious hazard with the use of the device **--> Definition from ISO 18113-1** Warnhinweis Angabe, die den Anwender über eine Situation alarmiert, die, sofern sie nicht vermieden wird, zu Gefährdungen oder sonstigen schwer wiegenden ungünstigen Folgen durch den Gebrauch eines *In-vitro*-Diagnostikums führen könnte ANMERKUNG 1: Die Bezeichnung einer Gefahrenwarnung als ein „Warnhinweis“ ist den meisten signifikanten Folgeerscheinungen vorbehalten. ANMERKUNG 2: Die Unterscheidung zwischen einem Warnhinweis und einer Vorsichtsmaßnahme (3.53) ist eine Frage des Grades, die die Wahrscheinlichkeit und Bedeutung der Gefährdung (3.20) berücksichtigt. ANMERKUNG 3: Der Gebrauch schließt **Anwendungsfehler** (3.71) und einen ziemlich vorhersehbaren Missbrauch ein. Siehe ISO 14971 und IEC 62366 zu einer Diskussion dieser Auffassungen. ANMERKUNG 4: Angepasst aus Literaturhinweis (U.S. Food and Drug Administration, Guidance on Medical Device Patient Labelling; Final Guidance for Industry and FDA, 19. April 2001) **Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers, 2001**

	Appendix E, Warnings and precautions: What are warnings and precautions? Warnings and precautions are written, pictorial, and/or audible alerts to a hazard. The term used to identify the particular hazard presents the reader with a cue to the seriousness of the hazard. A **warning** alerts the reader about a situation which, if not avoided, ***could result in death or serious injury***. [ANSI Z535.4-1998] It may also describe potential serious adverse reactions and safety hazards. The designation of a hazard alert as a ***"warning" is reserved for the most significant problems***. The term WARNING is generally used as the signal word for this type of hazard alert. If a problem may lead to death or serious injury, FDA may expect you to highlight the warning by placing it in a box. The distinction between warnings and precautions is a *matter of degree of likelihood and seriousness of the hazard*. The target audience for medical device labeling (health care practitioners and lay users of home use devices) generally recognize a hierarchy of hazard alerts, with ***warnings being those of a more serious nature*** and precautions being of a less serious, but important, nature. What is the purpose of warnings and precautions in medical device labeling? The basic purpose of a warning or precaution is twofold: · to inform users of potential personal and environmental hazards, and · to persuade them to modify their behavior to avoid injury or device damage. For a warning or precaution to be effective, readers must: · perceive the threat to be both severe and relevant to them, · believe that they can perform the recommended response, and · believe that response will be effective in avoiding the hazard. Effective warnings and precautions capture the reader's attention, are understood, are consistent enough with the reader's beliefs and attitudes to be accepted, and are persuasive enough to motivate the reader to comply. They invoke an appropriate level of fear arousal, conveying the nature and extent of the hazard, without being so strong that they backfire, causing the reader to select an alternative action or no action. **--> Definition from Device Labeling Guidance #G91-1** (Blue Book Memo) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/device-labeling-guidance-g91-1-blue-book-memo) Warnings Describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. Include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved. A warning is appropriate when the device is commonly used for a disease or condition for which there is a lack of valid scientific evidence of effectiveness for that disease or condition and such usage is associated with a serious risk or hazard.

2.3.4 Restrictions for Use

100 - Restrictions for Use

Restrictions on the use of the device, as defined by the manufacturer and achieved by the operating principle, are information that shall avoid a reduction in functionality or risks associated with the use environment.

KT Attributes	NA
Information for KT Application	**Context within the MDR** The term "restrictions for use" is mentioned within the MDR in the following context: • restrictions to the intended purpose of a device to certain groups of patients • restrictions imposed on certificates • combinations (with other devices or equipment) • known restrictions to combinations of devices and equipment • certain groups of patients • certain medical indications • limit on the duration of validity of the certificate
Binding Force of KT Title	--
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	**Current situation and opinion of the MDKU:** • There is no clear definition and differentiation between restrictions for use andlimitations of the device. • Restriction for use does not include contraindication, eg imposed by restricting the use for certain patient groups. • Restriction for use does not include restriction regarding certification. **Collins English Dictionary "restriction"** A restriction is an official rule that limits what you can do or that limits the amount or size of something. https://ell.stackexchange.com/questions/101556/limitation-restriction-vs-constraint • a "limitation" is an inability for something/someone. • a "restriction" is externally imposed to stop something, usually by law. e.g. device use in the vicinity of flammable liquids.
Existing regulatory definitions	**MDCG 2019-9:** "2.3. Anycontraindications or restrictions for use or limitations of the

	device shall be included." There are no particular definitions for the three similar terms. This MDCG guidance is the only document in which we find the particular term "restrictions for use".

2.3.5 Limitations of Use

110 - Limitations of Use

Limitations for use regarding the device define limitations for specific technical requirements, use environment, or user actions under which a medical device shall be used.

KT Attributes	Limitations on: • specific technical requirements • use environment • user actions
Information for KT Application	NA
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	
Existing regulatory definitions	**MDR:** Annex I General safety and performance requirements, CHAPTER III REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE 23. Label and instructions for use 23.1. General requirements regarding the information supplied by the manufacturer: (g) Residual risks which are required to be communicated to the user and/or other person shall be included as **limitations,** contra-indications, precautions or warnings in the information supplied by the manufacturer. 23.4. Information in the instructions for use: (s) information that allows the user and/or patient to be informed of any warnings, precautions, contra indications, measures to be taken and **limitations of use regarding the device**. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and **limitations of use regarding the device**. MDCG 2019-9 rev.1 2. Intended use of the device 2.1. Intended purpose 2.2. Indication(s) and target population(s) 2.3. Contraindications and/or **limitations** **ISO 24971:** **H.2.1.3 Analytical use:** Are there any additional **limitations for use** in specific use environments (e.g. medical laboratories, emergency room, operating room, ambulance, intensive care unit, neonatal care unit, nursing home, physician's office, screening clinics, or the patient's home)? **H.5.3: Limitations of the IVD medical device:** The limitations describe **situations in which** the *IVD medical* ***device*** **might not perform as intended and can therefore be a means of disclosing residual risks**, such as:

	— interfering substances not detectable by the user (e.g. drugs, biological metabolites); — specific patient populations in which the performance characteristics might not apply; — values outside the measuring interval (where performance characteristics are not validated); — patient populations where reference intervals or medical decision points might not apply; — primary sample types that have not been validated for the intended use; — circumstances and factors that might affect examination results, but have not been studied. **ISO 20417 - Medical devices — Information to be supplied by the manufacturer:** **6.6.2 Requirements for instructions for use** 6) ii) Residual risks shall be communicated as: I) limitations; II) contraindications; III) precautions; or IV) warnings **6.6.4 Requirements for technical description** c) 10) any known **limitations** (*what the user should not do*), contraindications, precautions and warnings; **Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers, 2001** What is appropriate content of an effective warning or precaution? [...] the consequences, specifying the serious adverse events, potential safety hazards and **limitations in device use** that result if users do not follow instructions. The purpose is to give them a clear idea of the risk, which is likely to increase compliance. **Collins English Dictionary, "limitation"** A limitation is a fact or situation that allows only some actions and makes others impossible. *This drug has one important limitation. Its effects only last six hours.* *...an acute disc collapse in the spine, causing limitation of movement.* *https://ell.stackexchange.com/questions/101556/limitation-restriction-vs-constraint* a "limitation" is an inability for something/someone. …. a "restriction" is externally imposed to stop something, usually by law.

2.4 Usability

2.4.1 Intended User

120 - Intended User

Intended users are users who, in accordance with the manufacturer's obligations, are intended to interact with the medical device during the entire product life cycle, in particular, but not exclusively, to achieve the effect claimed by the manufacturer.

KT Attributes	Users can interact with the medical device as part of different lifecycle activities, e.g. • transport • storage • installation • operation • maintenance and repair • disposal Furthermore, it can be differentiated between • Healthcare professional • Lay person
Information for KT Application	According to the wording used for usability engineering, there is a differentiation between Intended User and User Profiles: • "Intended User": the common interpretation of the term is that the intended users focuses on "main user" of the device responsible for the clinical application • The more detailed "User profiles" include beside "Intended User" the "Supportive Users" as well, e.g. surgical nurses or reprocessing staff
Binding Force of KT Title	Regulatory - Mandatory
Limitations	No
Description of known Limitations	NA
Source of KT Definition	Standards
Justification of KT Definition	The MDKU expert groups have decided that the definition of **IEC 62366-1** is the most appropriate definition and other regulatory sources provide additional information, e.g. attributes.
Existing regulatory definitions	**Input for KT definition:** 1. **MDR, Article 2(37):** means any healthcare professional or lay person who uses a device; 2. **IEC 62366-1:2015:** Person interacting with (i.e. operating or handling) the medical device.

	3. **MDCG 2023-3 "Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices"** : Question 5. Who is considered as the 'user' of a device? For the purpose of this document, the 'user' (Article 2(37) MDR) is any healthcare institution, healthcare professional or lay person (e.g. caregiver, patient) who uses the device, or persons installing or maintaining the device. The user of a device can also be referenced as the operator, e.g. in standards. **Input for application of KT:** 1. **EU MDR 2017/745 Annex 1:** • 4 (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate,training to users. • 5 (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users). • 23.4 (b) the device's intended purpose with a clear specification of indications, contra-indications, thepatient target group or groups, and of the intended users, as appropriate;

2.4.2 Normal Conditions of Use

130 - Normal Conditions of Use

Normal conditions of use of the medical device is an umbrella term that summarizes all information that define the normal use of a medical device.

KT Attributes	NA
Information for KT Application	Information related to the normal conditions of use are provided in the accompanying the product (e.g. by Labeling or IfU). That can include for example information about single use/reusable, reprocessing information, product life expectancy, expected service life, interoperability with other devices. Abnormal use is the use of a medical device outside the defined normal use
Binding Force of KT Title	Regulatory - Mandatory
Limitations	No
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	MDR does not provide a clear definition of what is meant by 'normal conditions of use' but the phrase is used several times.
Existing regulatory definitions	NA

2.4.3 Use Environment

140 - Use Environment

The use environment consists of the actual conditions and setting in which users interact with the medical device.

KT Attributes	NA
Information for KT Application	One medical device may be used in several use environments. The different use environments may also depend on the user's interactions such as transport, storage, installation, operation, maintenance and repair, and disposal. This KT only applies to intended use environment, it does not apply to use environment which are not intended in the context of reasonably foreseeable misuse.
Binding Force of KT Title	Regulatory - Mandatory
Limitations	No
Description of known Limitations	NA
Source of KT Definition	Standards
Justification of KT Definition	Existing definition is appropriate.
Existing regulatory definitions	IEC 62366-1:2015+AMD1:2020 3.20

2.4.4 User Group

150 - User Group

A user group summarizes a subset of users who are differentiated from other users by factors that are likely to influence their interactions with the medical device.

KT Attributes	NA
Information for KT Application	Several User Groups might exist per medical device. User Groups contain actual persons interact with a medical device, while User Profiles describe a set of actual persons interacting with the medical device. User Groups with primary users include User Profiles, who perform tasks that enable the intended purpose/intended use of the medical device. User Groups with secondary users include User Profiles, who do not perform tasks directly related to the intended purposes, such as maintenance, reprocessing, etc..
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	Standards
Justification of KT Definition	NA
Existing regulatory definitions	IEC 62366-1:2015+AMD1:2015, 3.25

2.4.5 User Profile

160 - User Profile

The user profile summarizes the mental, physical and demographic traits of a user group, as well as characteristics, such as knowledge including technical knowledge, skills, education, experience, training, and abilities as well as medical and physical conditions of the intended users, which can have a bearing on design decisions.

KT Attributes	NA
Information for KT Application	NA
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	Legislation
Justification of KT Definition	The definition from IEC 62366-1 was combined with MDR ANNEX I 5. b) as the description of users in the MDR applies to the user profile of IEC 62366-1.
Existing regulatory definitions	**1) MDR Annex I, 5. b):** *give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).* Remark: this definition refers to "intended user" and not to "user profile" - currently we have a KT for both... **2) IEC 62366-1:2015+AMD1:2020 3.29** User Profile

2.5 Clinical

2.5.1 Medical Purpose

170 - Medical Purpose

Medical purpose is the ability of a medical device (including accessories for medical devices) to be used for humans for health-related purposes such as

— 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;

— the control or support of conception;

— the cleaning, disinfection or sterilisation of devices.

Typically, the medical purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

KT Attributes	A medical purpose might be achieved by a medical device • **directly** (eg. hip-implant) or • **indirectly** (eg. a scalpel, supporting the implantation of a hip-implant).
Information for KT Application	In case that a device has no medical purpose, this data model element is not applicable for the particular device.
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Yes (See description of know limitations)
Description of known Limitations	Not all medical devices have a medical purpose.
Source of KT Definition	MDKU Specific
Justification of KT Definition	Medical purpose, intended purpose, indications for use are closely related to each other. To be able to name exact medical purpose as e.g. treatment, cure, diagnosis of disease intended purpose and indications for use, first shall be known. For the definition of intended purpose, knowledge about the expected device use for any medical purpose, non-medical purpose, or general consumption is required. The provided definition is indirectly based on the MDR definition for a medical device.
Existing regulatory definitions	**MDR, Main Chapters, Article 2, Definitions** (1) '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. **BfArM**: https://www.bfarm.de/EN/Medical-devices/_node.html Medical devices are products that have a medical purpose and are intended by the manufacturer for use in humans. In contrast to medicinal products that act pharmacologically, immunologically, or metabolically, the main intended purpose of medical devices is primarily achieved by physical means. **WHO**: https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices What are medical devices? Brief definition: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

2.5.2 Medical Condition(s)

180 - Medical Condition(s)

A medical condition is a health condition (pathologic or non-pathologic) that lies outside the range of normal age-appropriate human variation and normally requires medical treatment. A medical condition can include:

— disease/illness;

— injury/lesion;

— disorder;

— genetic or congenital defect;

— a biological or physiological condition;

— psychological condition;

— pregnancy/childbirth.

<table>
<tr><td>KT Attributes</td><td>NA</td></tr>
<tr><td>Information for KT Application</td><td>Medical Condition vs. Clinical Condition

There is no clear definition and differentiation between "medical condition" and "clinical condition"available in regulatory documents for medical devices.
MDCG 2020-7/ MDCG 2020-08 Section B (8) includes a foot note with a mixture of the terms "clinical condition" and "medical condition".
Therefore we conclude that the terms can be used synonymously.

<table>
<tr><td>Annex ADefinition "Indication" acc. MDCG 2020-6, chap. 1.2 (7), page 6</td><td>Annex BDefinition "Medcial condition" acc. MDCG 2020-07/ 2020-08 Section B (8)</td></tr>
<tr><td>Annex C‘indication’, ‘indication for use’: refers to the clinical condition that is to be
• diagnosed,
• prevented,
• monitored,
• treated,
• alleviated,
• compensated for,
• replaced,
• modified,
• or controlled by the medical device.</td><td>Annex DMedical condition(s): It refers to the clinical condition that is to be
• diagnosed,
• prevented,
• monitored,
• treated,
• alleviated,
• compensated for,
• replaced,
• modified
• or controlled by the medical device.</td></tr>
</table>
</td></tr>
</table>

	Clinical condition might be used synonymously, but it is highly recommended to only use "Medical Condition" to ensure a clear, precise regulatory language.
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Yes (See description of know limitations)
Description of known Limitations	All devices have an intended purpose/intended use, but not all devices are used for a defined medical condition.
Source of KT Definition	Guidance
Justification of KT Definition	No clear definition and differentiation between "medical condition" and "clinical condition" available in regulatory documents for medical devices. MDCG 2020-7/ MDCG 2020-08 Section B (8) includes a foot note with a **mixture** of "clinical condition" and "medical condition". Therefore a separate proposal for the term "Medical Condition" has been made. The new proposal is based on source: https://www.lawinsider.com/dictionary/medical-condition --- German: -> Medical Condition = Gesundheitszustand / Mediziner Zustand = in deutscher MDR wird "Krankheitszustand" verwendet (z.B. Schwergrad der Krankheit?) -> Clinical Condition = Krankheitsbild / Klinischer Zustand --> Beschreibung des Zustands des Patienten (z.B. Durchfall, Fieber,... sonstige Symptome) -> Indication = Indikation Klinisch ist ein Begriff der medizinischen Umgangssprache, der je nach Kontext verschiedene Bedeutungen haben kann. Meistens wird klinisch als Kurzform für "klinische Zeichen" oder das "klinische Bild", also für direkt erkennbare Symptome und Beschwerden des Patienten benutzt. Der Begriff dient dabei zur Abgrenzung gegenüber anderen, "paraklinischen" Formen der Diagnostik. Beispiele: Klinisch hat der Patient Durchfall, in der Stuhluntersuchung wurden Noroviren festgestellt. Der Stuhl war positiv auf Noroviren, der Patient hat aber keine Klinik (d.h. keinen Durchfall und/oder Erbrechen). [see here]. ------- Wikipedia, Disease: • Diseases are often known to be **medical conditions** that are associated with specific signs and symptoms. • A **medical condition** or **health condition** is a broad concept that includes all diseases, lesions, disorders, or non-pathologic condition that normally receives medical treatment, such as pregnancy or childbirth. • The term medical condition ... describes an individual patient's current state from a medical standpoint

Existing regulatory definitions	**MDCG 2020-7/ 2020-08 Section B (8) (page 6)** *"Medical condition(s)" - Refers to the clinical condition that is to be* • *diagnosed,* • *prevented,* • *monitored,* • *treated,* • *alleviated,* • *compensated for,* • *replaced,* • *modified,* • *controlled* *by the medical device."*

2.5.3 Medical Procedure

190 - Medical Procedure

A medical procedure is an activity directed at or performed on an individual with the aim of improving health, treating disease or injury, or making a diagnosis.

KT Attributes	NA
Information for KT Application	NA
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Yes (See description of know limitations)
Description of known Limitations	Not all medical devices are used for a specific medical procedures. Instead, for some medical devices only a particular indication might be defined.
Source of KT Definition	MDKU Specific
Justification of KT Definition	We did not find any valuable source of a definition within the general regulatory sources, but found one by a medical dictionary instead.
Existing regulatory definitions	**Mentioned in MDR**, Article 22 - System & Procedure Packs:"*... (c) other products which are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified....*" **MEDDEV 2.7.1 rev.4; A12.4.** Notified body specific procedures and expertise: The assessment team should have sufficient expertise in the device technology as the associated **medical procedures**. **Wikipedia**: https://en.wikipedia.org/wiki/Medical_procedure A **medical procedure** is a course of action intended to achieve a result in the delivery of healthcare. A medical procedure with the intention of determining, measuring, or diagnosing a patient condition or parameter is also called a medical test. Other common kinds of procedures are therapeutic (i.e., intended to treat, cure, or restore function or structure), such as surgical and physical rehabilitation procedures. **Other sources of definitions*:*** • "An activity directed at or performed on an individual with the object of improving health, treating disease or injury, or making a diagnosis."[1] - International Dictionary of Medicine and Biology • "The act or conduct of diagnosis, treatment, or operation."[2] - Stedman's Medical Dictionary by Thomas Lathrop Stedman • "A series of steps by which a desired result is accomplished."[3] - *Dorland's Medical Dictionary* by William Alexander Newman Dorland

	"The sequence of steps to be followed in establishing some course of action."[4] - Mosby's Medical, Nursing, & Allied Health Dictionary

2.5.4 Indications

200 - Indications for Use

Indications for use for a medical device provide the reason for use of the device and take into account e.g. medical procedures, participation of the device within the medical procedure, and medical condition of a patient only if relevant.

KT Attributes	NA
Information for KT Application	The indications for use for a medical device shall consider e.g. the medical procedures, participation of the device within the procedure, medical condition of a patient (only if relevant). A particular indication for an individual medical device may differ depending on respective features, characteristics and other factors related to these medical device.
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Yes (See description of know limitations)
Description of known Limitations	Not all medical devices are used for a particular indication. Instead, some medical devices are used for a particular medical procedure.
Source of KT Definition	Guidance
Justification of KT Definition	Definition in MDR is not correct. Indication and disease is not identical: "An indication can commonly be confused with the term diagnosis. A diagnosis is the assessment that a particular [medical] condition is present while an**indication is a reason for use**. [3] The **opposite of an indication is a contraindication**, [4] a reason to withhold a certain medical treatment because the risks of treatment clearly outweigh the benefits." Source: https://en.wikipedia.org/wiki/Indication_(medicine) Existing regulatory documents to not use the term "indication" according in the way. Not all medical devices have a clear indication as part of the intended purpose. Therefore many medical device manufacturers describe a medical procedure instead. At the end, it is important that at least the indication(s) or medical procedure is described for each medical device. Clinical condition refers to the patient state of health based on symptoms and test results. On the other hand a medical condition refers to a specific disease. Nevertheless it is not defined in the text of the MDR, the terms are used in different sections without clear destinction.
Existing regulatory definitions	**MDCG 2020-6, chap. 1.2 (7), page 6** *"'indication', 'indication for use': refers to the clinical condition that is to be* • *diagnosed,* • *prevented,* • *monitored,*

- *treated,*
- *alleviated,*
- *compensated for,*
- *replaced,*
- *modified*
- *or controlled by the medical device.*

It should be distinguished from 'intended purpose/intended use', which describes the effect of a device. All devices have an intended purpose/intended use, but not all devices have an indication (e.g. medical devices with an intended purpose of disinfection or sterilisation of devices)."

"All devices have an intended purpose/intended use, but not all devices have an indication (e.g. medical devices with an intended purpose of disinfection or sterilisation of devices)."[MDCG 2020-6, chap. 1.2 (7), page 6]

Connection of "Medical Condition", "Clinical Condition" and "Indication":

• Definition "Indication" acc. MDCG 2020-6, chap. 1.2 (7), page 6	• Definition "Medcial condition" acc. MDCG 2020-07/ 2020-08 Section B (8)
• 'indication', 'indication for use': refers to the clinical condition that is to be • diagnosed, • prevented, • monitored, • treated, • alleviated, • compensated for, • replaced, • modified, • or controlled by the medical device.	• Medical condition(s): It refers to the clinical condition that is to be • diagnosed, • prevented, • monitored, • treated, • alleviated, • compensated for, • replaced, • modified • or controlled by the medical device.

MDCG 2019-9, chap. 2.2, page. 12
"The indications shall be described. This includes the stages and/or severities of the pathologies, the specific medical conditions, and the specific anatomical locations or confirmation that no anatomical locations are contraindicated, as applicable. The target population(s) shall be specified, for example if the device is intended for adults and/or children and/or infants/neonates."

	To be shown in **PSUR** according to MDCG 2022- 2021 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR), December 2022, Annnex I under *Description of the devices: "The intended purpose of the device(s) as per the Instructions for Use according to Annex I, Chapter III, 23.4(b) MDR, any indications, contra-indications, and target populations",* as appropriate Also in the **PMS Report** based on statement in MDCG 2022-2021 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR), December 2022, *"according to Manufacturers of class I devices do not have to prepare a PSUR; instead, they should prepare a Post-Market Surveillance Report (PMSR) as detailed in Article 85. This guidance, although not covering PMSR, may provide useful suggestions on how information can be presented.*

2.5.5 Contra-indications

210 - Contra-indications

A contra-indication is a condition or factor related to the patient that makes the use of a medical device or procedure improper or inadvisable.

KT Attributes	• Absolute
	  • using the device poses unacceptable risk to the patient
	  • procedure poses unacceptable risk to the patient
	• Relative
	  • using the device poses additional risk to the patient, while the benefits may outweigh risks
	  • procedure poses additional risk to the patient, while the benefits may outweigh risks

Information for KT Application	Contraindications (may be absolute or relative) are concerning patient groups's conditions or situations in which a medical device should not be used because it can potentially cause harm to the patient. In comparison, restrictions for use and limitations of use regarding the device are related to the user/healthcare environment.
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	There is no definition specifically for medical devices available.

Existing regulatory definitions	**Mentioned in:**
	• MDR
	  • Article 32, 2 b)
	  • Annex I, Chapter III, 23.4 s) & t)
	  • Annex XIV, Part B, 6.1 b)
	  • Annex XV, Chapter II, 2.5
	• MDCG 2020-13
	• MDCG 2020-08
	• MDCG 2020-07
	• MDCG 2020-06
	• MCDG 2019-9
	• ISO 14971
	• IMDRF GRRP WG (PD1)/N52
	--> Definition is only given in IMDRF GRRP WG (PD1)/N52, but we decided not to take it because it excludes "relative" contraindications.

	Input for definition: • PubMed MeSH Term Contraindication A condition or factor associated with a recipient that makes the use of a product, procedure, or physical agent improper or inadvisable. Contraindications may be absolute (life threatening) or relative (higher risk of complications in which benefits may outweigh risks). • FDA Guidance - Patient Labeling Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit. There may be persons in whom the device should not be used because of their health status. For example, the device may be contraindicated for pregnant women. List known and reasonably foreseeable hazards, not theoretical possibilities. For example, if hypersensitivity to a material in the device has not been demonstrated, it should not be a contraindication. However, if hypersensitivity to a material has not been sufficiently studied and/or is not scientifically documented, clearly state that information. Contraindications to the use of a device could include: · demonstrated hypersensitivity to a material where there is patient contact with the device, · substantial risk of being harmed because of patient characteristics (e.g., age, gender, accompanying therapy, disease state, health status), or · continued use in the face of an unacceptably hazardous adverse event • IMDRF Guidance - Labeling Medical Devices & IVD 3.4 Contraindication: Labelling elements that describe situations, such as patient populations, medical reasons, or clinical conditions, in which the device should not be used because the risk of use clearly outweighs any possible benefit. --> Definition from Device Labeling Guidance #G91-1 (Blue Book Memo) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/device-labeling-guidance-g91-1-blue-book-memo) Contraindications This section describes situations in which the device should not be used because the risk of use clearly outweights any possible benefit. Examples that may, but not always, contraindicate the use of a device include: Hypersensitivity to an ingredient of a permanently implanted device; Substantial risk of being harmed because of age, sex, concomitant therapy, disease state or other condition; or, Continued use in the face of an unacceptably hazardous adverse reaction. Known hazards and not theoretical possibilities are to be listed, e.g., if hypersensitivity to an ingredient in the device has not been demonstrated, it should not be listed as a contraindication. The "Contraindications" section shall immediately follow the "Indications for Use" section of the labeling. If no contraindications are known, this section of the labeling should state "None known." **Information for KT application:** To be shown in **PSUR** according to MDCG 2022- 2021 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR), December 2022, Annnex I under *Description of the devices: "The intended purpose of the device(s) as*

	per the Instructions for Use according to Annex I, Chapter III, 23.4(b) MDR, any indications, contra-indications, and target populations", as appropriate Also in the **PMS Report** based on statement in MDCG 2022-2021 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR), December 2022, *"according to Manufacturers of class I devices do not have to prepare a PSUR; instead, they should prepare a Post-Market Surveillance Report (PMSR) as detailed in Article 85. This guidance, although not covering PMSR, may provide useful suggestions on how information can be presented.* For **PMS Plan** best practice.”

2.5.6 Complications

220 - Device use related Complications

Device use related complications are abnormal effect(s) occurring during or after in the course of a medical procedure and related to the usage of a medical device or the procedure itself.

KT Attributes	Cause of a complication: • caused by inappropriate design • caused by inappropriate manufacturing • caused by inappropriate use Occurence of a complication: • seen immediately during performed medical procedure • seen after performed medical procedure Awareness: • expected • unexpected
Information for KT Application	Complications lead to adverse events or incidents.
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	• Complication are not defined nor mentioned in MDR nor in ISO 14971. • They are mentioned in MEDDEV 2.7./1 Rev. 4., MDCG 2020-10-1 and 2021-6, but without a definition. • Existing medical definitions focus on medical complications that are unrelated to a medical device use. Therefore we propose a new definition in the context of medical device use.
Existing regulatory definitions	The term is mentioned in: **1) MEDDVEV 2.7/1Rev.4** **2) MDCG 2020-10-1** "The sponsor and the investigators will distinguish between the serious adverse events related to the investigational device and those related to the procedures (any procedure specific to the clinical investigation). An adverse event can be related both to procedures and the investigational device.**Complications** caused by concomitant treatments not imposed by the clinical investigation plan are considered not related. Similarly, several routine diagnostic or patient management procedures are applied to patients regardless of the clinical investigation plan. If routine procedures are not imposed by the clinical investigation plan, complications caused by them are also considered not related."

	3) MDCG 2021-6 "Additional procedures which are burdensome can include a wide variety of different interventions, this may include procedures which may cause pain, discomfort, fear, potential risks or**complications**/side-effects, disturbances of lives and personal activities, or otherwise unpleasant experiences. It is mostly determined from the perspective of the person bearing the burden." Additional Input: **Collin dictionary "complication":** COMPLICATION Definition und Bedeutung | Collins Wörterbuch (collinsdictionary.com) A **complication** is a problem or difficulty that makes a situation harder to deal with. A **complication** is a medical problem that occurs as a result of another illness or disease. *Blindness is a common complication of diabetes. [+ of]* *He died of complications from a heart attack. [+ from]* **complication in American English** **1.** the act of complicating, or making involved **2.** a complicated condition or structure; complex, involved, or confused relationship of parts **3.** a complicating factor or occurrence as in the plot of a story or in the unfolding of events **4.** *Medicine* a second disease or abnormal condition occurring during the course of a primary disease

2.5.7 Undesirable side-effects

230 - Undesirable side-effects

An undesirable side-effect is any unintended and unwanted medical manifestation in the human body, as a consequence of the intended use of a device.

KT Attributes	• Expected (known) • Unexpected (unknown)
Information for KT Application	**Information for KT application:** • Undesirable side-effects are not the result of a malfunction, deterioration in the device's characteristics or performance, or an inadequacy in the information supplied by the manufacturer. • An unsuccessful treatment (treatment failure), or consequences from misuse should not be considered an undesirable side effect. • Expected side-effects must be evaluated in the Risk Analysis AND Clinical Evaluation • Expected side-effects must be mentioned in the Instruction Manual (IFU). • (New) Unexpected side-effects are identified via PMCF/PMS data or Clinical Evaluation and records referring to any undesirable sideeffects. should be considered in the PSUR/PMS Report • (New, unknown) unexpected side-effects are later expected side-effects, when documented in the Risk Analysis. Application for PMS: **MDR ANNEX III: 1.1 (a):** The post-market surveillance plan shall address the collection and utilization of available information...[on] data on any undesirable side-effects; **MDCG 2022-21, ANNEX III:** The manufacturer should assess the data in relation to the thresholds concerning known risks and **side effects** and benefits intended to be gained.
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	Guidance
Justification of KT Definition	
Existing regulatory definitions	**1) German definition** from "Nationalen Arbeitskreis zur Implementierung der EU-Verordnungen MDR/IVDR des Bundesgesundheitsministerium", Source: BMG - FAQ Vigilanz: *„Nebenwirkung" bezeichnet einen unbeabsichtigten, meist unerwünschten Effekt bei Patienten, Anwendern oder Dritten, der beim bestimmungsmäßigen Gebrauch eines Medizinprodukts im Zusammenhang mit dem gewünschten Effekt auftritt und auf*

	die Anwendung des Produkts zurückzuführen ist, und der nicht auf eine Fehlfunktion, Verschlechterung der Eigenschaften oder Leistung oder eine Unzulänglichkeit der vom Hersteller bereitgestellten Informationen zurückzuführen ist. *"Side-effect means an unintended effect, usually undesirable, on patients, users or other persons, which occurs during the intended use of a medical device in connection with the desired effect and which is related to the use of the device, and which is not due to a malfunction, deterioration in the characteristics or performance, or inadequacy in the information supplied by the manufacturer."* **2) MDCG 2023-03, Q&A-8.:** An 'undesirable side-effect' under the MDR should be understood as any unintended and unwanted medical manifestation in the human body, as a consequence of the normal use of a device.[17] Undesirable side-effects are not the result of a malfunction, deterioration in the device's characteristics or performance, or an inadequacy in the information supplied by the manufacturer. An unsuccessful treatment (or treatment failure) should not be considered an undesirable side effect. For the purpose of this guidance, undesirable side-effects can be expected or unexpected and are considered as incidents under the MDR (Article 2(64) MDR). Footnote 17 from MDCG 2023-03: It should be noted that the terms 'undesirable side-effects' and 'side-effects' are used synonymously in the MDR.

2.5.8 Intended Patient Population

240 - Intended Patient Population

The intended patient population refers to the specific group of patients for whom the medical device is designed to be used. Referenced patient populations refer to the natural states of human being.

KT Attributes	• No clinical use (device is not directly used for patients) • No restriction of the patient population (fetuses do not belong to the regular patient population) • Restrictions of the patient population, e.g: device can be used for defined patient population (examples see information for KT application)
Information for KT Application	**Patient Population related information** Specific medical conditions of patients to be diagnosed, treated, and/or monitored, etc. are referenced by "indications for use" (if relevant). Restrictions within a defined intended patient population, because of specific medical conditions of patients, are referenced by contra-indications (if relevant). **Use of Attributes** Attributes depend on required level of detail for a specific devices, e.g. age, gender, anatomy, physiology, possibly other aspects (MEDDEV 2.7/1 rev. 4, Appendix A1). There are several guidances for grouping of patients. Here is one example in accordance with Ages of patient groups are classified according to the National Association of Statutory Health Insurance Physicians Berlin 2023: • Fetuses • Premature neonates (born alive before 37 weeks of pregnancy) • Neonates (up to the completed 28th day of life) • Infants (from the beginning of the 29th day of life until the end of the 12th month) • Toddlers (from the beginning of the 2nd to the end of the 3rd year of life) • Children (from the beginning of the 4th to the end of the 12th year of life) • Adolescents (from the beginning of the 13th to the completed 18th year of life) • Adults (from the beginning of the 19th year of life) • Women • Men • Obese patients (BMI of 30 or higher) • Pregnant women • Brest feeding women • Others, e.g. ethnicity, skin colour, non-binary/divers, kilogram specification

	In the practical use of this KT an overview might be given about the intended patient populations or it might be possible to describe each patient group in a separate KU. "Intended patient population" is identical as "Patient Population" (see ISO 14791).
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	MDR requires the definition of intended patient population to be very specific, but at the same time doesn't provide profund definition. The suggested definition allows an unambiguous definition of intended patient groups.
Existing regulatory definitions	

2.5.9 Size of Patient Population

250 - Size of Patient Population

The size of the patient population refers to the number of individuals included in the defined patient population.

KT Attributes	If applicable and depending on the context of the provided information, it might be possible to differentiate between the number of patients that • have been exposed to a subject medical device • have been exposed to a similar/equivalent medical device • have been treated with alternative methods • are part of medical epidemiological groups/statistics • are part of a clinical investigation/PMCF study
Information for KT Application	**MDCG 2022-21** provides examples in Annex II (Templates for the Presentation of Data in the PSUR) regarding the presentation of information. However, keep in mind that it is up to the manufacturer to present data in the most appropriate manner, depending on the nature of the data and the device. The number of patients exposed by the device may be relevant for benefit-risk assessment, but details are not defined in the MDR.
Binding Force of KT Title	Best practice
Limitations	Yes (See description of know limitations)
Description of known Limitations	It might not be possible for all medical devices to accurately define the size of the patient population.
Source of KT Definition	MDKU Specific
Justification of KT Definition	There is no clear definition of the term. The term "Size of patient population" is a pretty broad term. Different meanings are possible: e.g. number of patients have been exposed to the device or similar/equivalent devices, treated with alternative methods, size of patient population involved in a clinical study, etc. Size of patient population involved in a clinical study is relevant for strength of evidence provided within clinical evaluation, but not for definition of intended use. Therefore a new definition and attributes have been proposed. MDCG 2022-21 (for PSUR) gives a detailed guidance how to present and structure the data of this KT. The KT itself is required by MDR Article 86.1
Existing regulatory definitions	**MDR, Article 86.1c** (c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device. **MDCG 2022-21 Annex I: Template for the PSUR, Chapter: Size and other characteristics of the population using the device (acc. Article 86.1 MDR)**

	• Evaluate how many patients have been exposed to the device and the characteristics of the exposed patient group(s). • Estimate the number of patients exposed, as the sales numbers alone do not necessarily reflect the number of uses of the device (usage frequency). There aredifferent scenarios as: Active devices may have a lifetime of several years with multiple uses each day, resulting in high number of patients exposed to the device(e.g. CTs). In case of implants, multiple devices may be used in one patient, e.g.several bone screws in one surgery. For other devices, the sales numbers directlycorrelate with the patient number exposed to the device. • Describe the usage of the device in different patient populations and when available compare it to the expected usage and identify the possible over-represented or under-represented patient groups if clinically relevant and known by the manufacturer. • When possible, consideration should be given to patient demographic aspects. • When applicable, evaluate the effect of the detected changes to findings obtained previously and in the current PSUR. **MDCG 2022-21 Annex II: Templates for the Presentation of Data in the PSUR**

2.5.10 Part of the body or type of tissue interacted with

260 - Part of the body or type of tissue interacted with

The part of the body or type of tissue interacted with defines the region or part of the human body or the type of tissue with which the medical device interacts during its intended use.

KT Attributes	• Central nervous system (brain, spinal cord, spinal nerves, liquor cerebrospinalis) • Peripheral nervous system (nerves, nerve plexus, nerve roots; sensory and motor parts) • Autonomic nervous system (truncus sympathicus and sympathic fibers, n. vagus) • Sensory systems (nervous sub-systems: visual system, olfactory system, taste (gustatory system), hearing (auditory system)) • Central circulatory system (heart and cardiac vessels, main blood vessels (aorta thoracalis and abdominalis, vena cava superior and inferior, pulmonary vessels) • Peripheral circulatory system (blood, arteries, veins, capillaries) • Skeletal system (bones, cartilage, joints, ligaments and tendons) • Muscular system (skeletal muscles, smooth muscles) • Lymphatic system (lymph, lymph nodes, lymph vessels, tonsils, spleen, thymus) • Respiratory system (nose, outh, paranasal sinuses, pharynx, larynx, trachea, bronchi, lungs and thoracic diaphragm) • Digestive system (teeth, tongue, salivary glands, esophagus, stomach, liver, gallbladder, pancreas, small intestine, large intestine, rectum and anus) • Endocrine system (hypothalamus, pituitary, pineal gland, thyroid, parathyroid glands, and adrenal glands, ovaries, testes) • Urinary system (kidneys, ureters, bladder and urethra) • Reproductive system (ovaries, fallopian tubes, uterus, vagina, mammary glands, penis, testes, vas deferens, seminal vesicles and prostate) • Integumentary system (skin, hair, exocrine glands, fat, and nails)
Information for KT Application	This KT must be considered in the risk management file to evaluate biological risks.

Binding Force of KT Title	Regulatory - Mandatory
Limitations	Yes (See description of know limitations)
Description of known Limitations	Not all medical devices have an interaction with the human body/type of tissue. E.g. for software as medical device, this KT is not applicable.
Source of KT Definition	MDKU Specific
Justification of KT Definition	There is no clear definition available, but similar terms are found - without an explanation - in the MDR, Annex VIII, Annex VII, ISO 10993 and MDCG 2020-5. Body site is too general/big to describe the interaction with the MD.
Existing regulatory definitions	NA

2.5.11 Type of application

270 - Type of application/contribution to medical purpose

The type of application/contribution to the medical purpose describes the type of the involvement of a medical device in a medical or technical procedure to achieve the medical purpose of the device.

KT Attributes	There can be a • Direct application/contribution • Indirect application/contribution for diagnosis / prevention / monitoring / therapy /compensation / replacement / modification / control of clinical / medical condition of the patient.
Information for KT Application	The intention of this term is to be able to name the type of the medical purpose as e.g. treatment, cure, diagnosis of disease intended purpose and indications for use, first shall be known. "Type of application" and "intended application" might be used synonymously.
Binding Force of KT Title	Best Practice
Limitations	Unknown (not defined)
Description of known Limitations	NA
Source of KT Definition	MDKU Specific
Justification of KT Definition	The definition for this KT arises from the practical need to describe what type of application a medical device is used for. The indication acc. to MDCG 2020-6 served as input in that it takes the perspective of the opposite side, namely the description of the indication for which a particular medical device could be specific. For medical devices with indirect clinical benefit an indication is often not relevant, etc. is related to the illness, disability, to be treated, diagnosed, etc.
Existing regulatory definitions	The MDCG 2020-6 provides an indirect definition (perspective on the indication): ‘indication’, ‘indication for use’: refers to the condition that is to be • diagnosed, • prevented, • monitored, • treated, • alleviated, • compensated for, • replaced, modified • or controlled by the medical device

2.5.12 Clinical Benefit

280 - 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

KT Attributes	benefit classification: for patient health (direct/ indirect), for clinical management (incl. benefit/advantage for the user), for public health • direct benefit - direct diagnostic/ therapeutic effect for the patient health caused by the medical device • indirect benefit - participation of device within a medical procedure and only the performed medical procedure can provide benefit for the patient, but not the device alone. • type of benefit (concrete benefit) • magnitude of benefit • likelihood of benefit • duration of benefit • measurable by outcome parameters
Information for KT Application	
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	Measurement of indirect clinical benefit resulted by a device is extremely difficult due to too many factors influencing the outcome of a medical procedure.
Source of KT Definition	Legislation
Justification of KT Definition	Definition in MDR is clear and suitable.
Existing regulatory definitions	MDR, Article 2, (53): ‘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;

2.5.13 Clinical Performance

290 - Clinical Performance

Clinical Performance means the measurable ability of a medical device leading to a clinical benefit for patients (if needed compared to the State of the Art), when used as intended by the manufacturer.

If clinical benefit is proven, then clinical performance can be stated to be achieved. Clinical benefit can be resulted from any direct or indirect medical effects which stem from its technical or functional characteristics, to achieve its intended purpose as claimed by the manufacturer.

KT Attributes	• achieved / not achieved • inferior / non-inferior / better in comparison to the State of the Art.
Information for KT Application	
Binding Force of KT Title	Regulatory - Mandatory
Limitations	Unknown (not defined)
Description of known Limitations	
Source of KT Definition	--
Justification of KT Definition	Based on the original definition of Article 2 (52) is further clarification of the relationship between clinical performance and clinical benefit: If clinical benefit is proven, then clinical performance can be stated to be achieved. Clinical benefit can be resulted from any direct or indirect medical effects which stem from its technical or functional characteristics, to achieve its intended purpose as claimed by the manufacturer. Annotation: definition of a medical device must be linked to the clinical performance.
Existing regulatory definitions	**Input for KT definition:** MDR, Article 2, (52): '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; "... (49) The summary of safety and clinical performance for a device should include in particular the place of the device in the context of diagnostic or therapeutic options taking into account the clinical evaluation of that device when compared to the diagnostic or therapeutic alternatives and the specific conditions under which that device and its alternatives can be considered..."