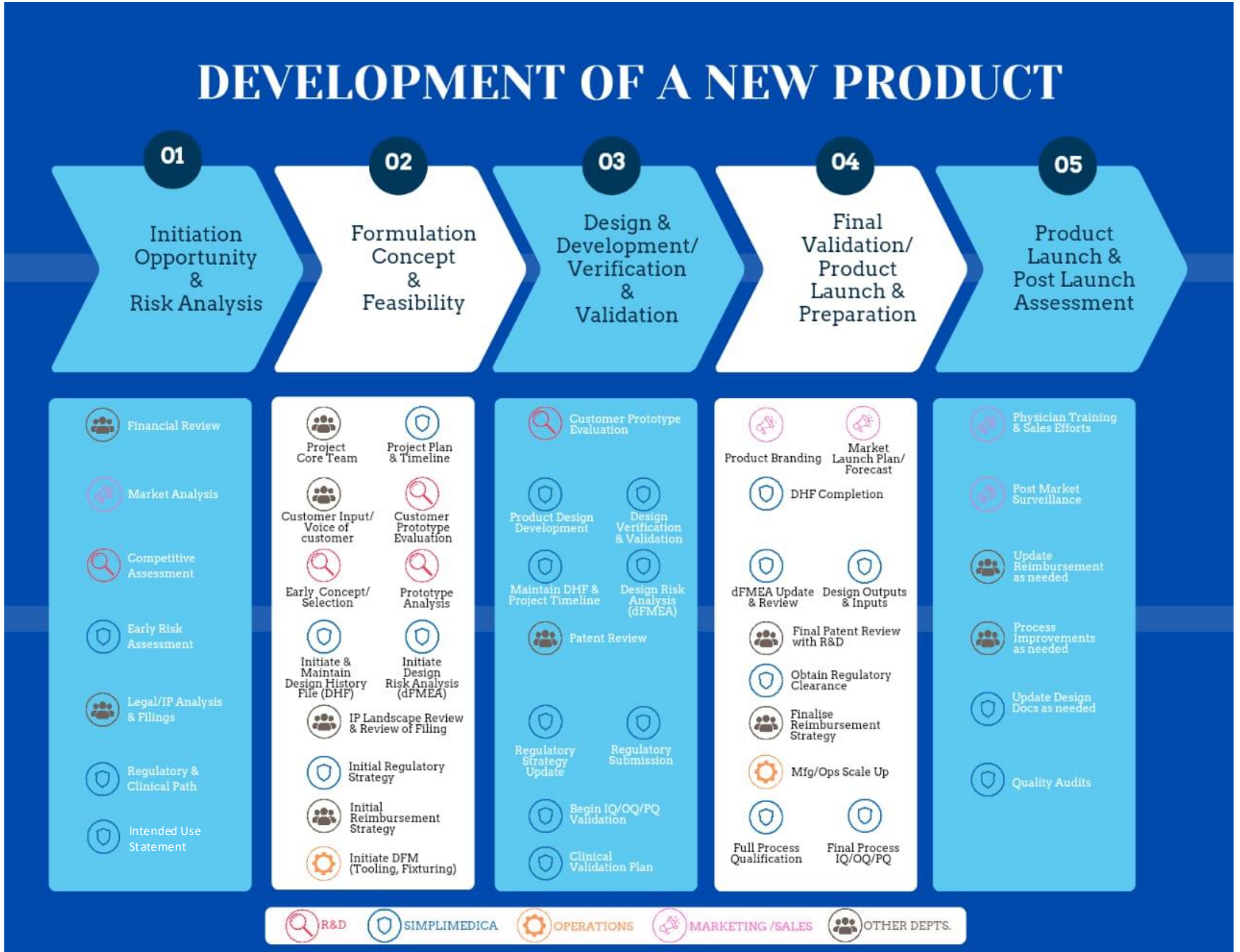
SIMPLIMEDICA

SIMPLIFYING DEVICE REGULATIONS

Intended Use – the beginning and the end of the regulatory journey

What we will look at

- Medical Device Definition
- Intended Use
- Intended Purpose
- Indications for Use
- Instructions for Use
- Writing an Intended Use Statement - Examples


DEVELOPMENT OF A NEW PRODUCT
01
Initiation Opportunity & Risk Analysis
02
Formulation Concept & Feasibility
03
Design & Development/ Verification & Validation
04
Final Validation/ Product Launch & Preparation
05
Product Launch & Post Launch Assessment
Financial Review
Market Analysis
Competitive Assessment
Early Risk Assessment
Legal/IP Analysis & Filings
Regulatory & Clinical Path
Intended Use Statement
Project Core Team
Project Plan & Timeline
Customer Input/ Voice of customer
Customer Prototype Evaluation
Early Concept/ Selection
Prototype Analysis
Initiate & Maintain Design History File (DHF)
Initiate Design Risk Analysis (dFMEA)
IP Landscape Review & Review of Filing
Initial Regulatory Strategy
Initial Reimbursement Strategy
Initiate DFM (Tooling, Fixturing)
Customer Prototype Evaluation
Product Design Development
Design Verification & Validation
Maintain DHF & Project Timeline
Design Risk Analysis (dFMEA)
Patent Review
Regulatory Strategy Update
Regulatory Submission
Begin IQ/OQ/PQ Validation
Clinical Validation Plan
Product Branding
Market Launch Plan/ Forecast
DHF Completion
dFMEA Update & Review
Design Outputs & Inputs
Final Patent Review with R&D
Obtain Regulatory Clearance
Finalise Reimbursement Strategy
Mfg/Ops Scale Up
Full Process Qualification
Final Process IQ/OQ/PQ
Physician Training & Sales Efforts
Post Market Surveillance
Update Reimbursement as needed
Process Improvements as needed
Update Design Docs as needed
Quality Audits
R&D
SIMPLIMEDICA
OPERATIONS
MARKETING /SALES
OTHER DEPTS.

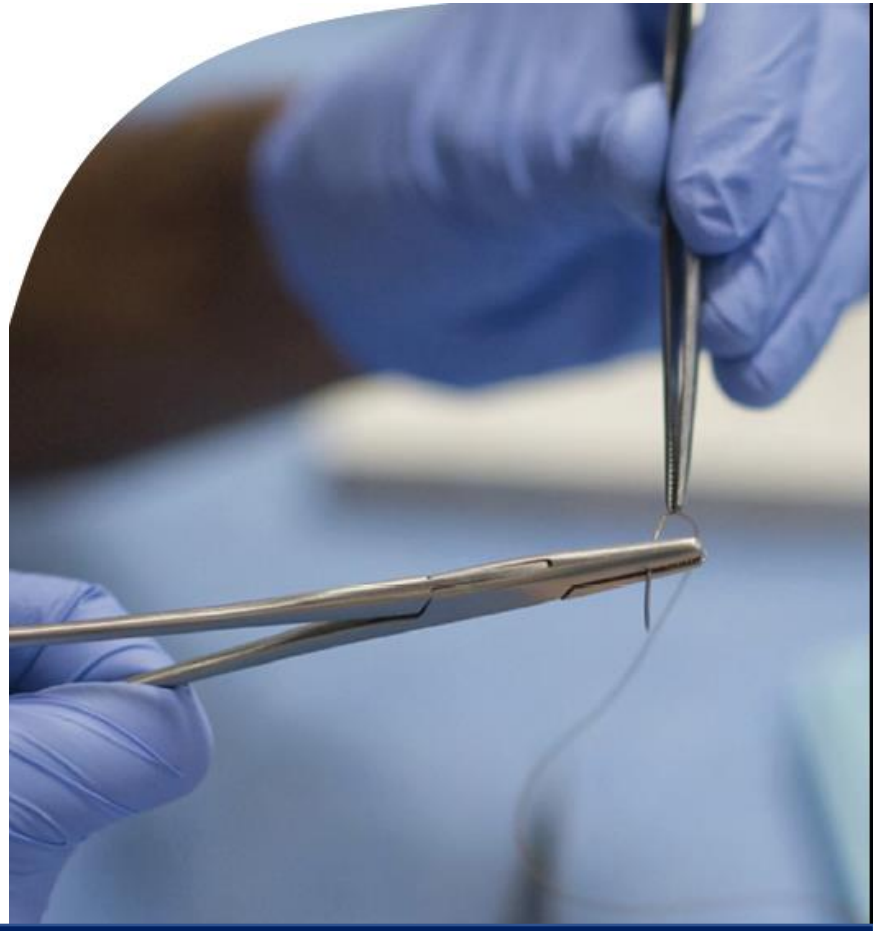
Intended Use

The intended use of a medical device describes the general purpose of the device or its function. Intended use may branch off into intended purpose, indications for use, and instructions for use, which are all interlinked. The importance of intended use is highlighted in many different medical device regulations.

Medical Device

According to WHO, the definition of a medical device is:

'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.'



Examples include:

- Single use devices – syringes, catheters
- Imaging – ultrasound, CT scanner
- Personal protective equipment (PPE) – gown, gloves
- Implants – hip prosthesis, pacemakers
- Surgical equipment – scissors, forceps
- Medical equipment – patient monitors, anaesthesia machines

Medical Device

According to FDA, the definition of a medical device is:

Per Section 201(h)(1) of the Food, Drug, and Cosmetic Act, a device is:

‘An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, – intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or – intended to affect the structure or any function of the body of man or other animals

And does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. – The term "device" does not include software functions excluded pursuant to section 520(o).

Medical Device

According to EU, the definition of a medical device is:

A 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 sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

US FDA – 21 CFR

Intended Use: The general purpose of the device or its function. This includes the indications for use.

Indications for use: is defined as ‘a general description of the disease or condition the device is intended to diagnose, treat, prevent, cure or mitigate, or affect the structure or function of the body, including a description of the patient population for which the device is intended.

Statement of ‘Indications for Use’ for 510(k) should include:

- specific indications
- clinical settings
- define the target population
- anatomical sites
- be consistent with labelling, advertising and instructions for use

EU MDR – 2017/745

Intended use

The EU MDR refers to the intended use/user of a medical device **31 times** to ensure that the manufacturer:

- Eliminates and evaluates risks associated with intended use (Annex I, clause 3, part C)
- Designs, manufactures, and packages the device in a way that does not affect its performance during its intended use (Annex I, clause 7)
- Documents the risks associated with the intended use of the device (Annex VII, clause 4.5.2, part b)
- Performs a clinical evaluation to evidence conformity with general safety and performance requirements under normal conditions of the intended use (Article 61.1)

The EU IVDR 2017/746 also refers to the intended use/user of a medical device **38 times**.

EU MDR – 2017/745

Intended purpose

The intended purpose of a medical device is mentioned **87 times** in the **EU MDR** and **76 times** in the **EU IVDR**.

According to these regulations, the intended purpose is defined as ‘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’.

Key points include:

- Ensuring the device meets safety and performance requirements in accordance with its intended purpose (Article 5.2)
- Conducting a clinical evaluation of the literature relating to the intended purpose of the device (Article 61.3)

EU MDR – 2017/745

Instructions for use

The EU MDR also refers to instructions for use **40 times.** This is defined as ‘the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken’.

Key points include:

- The device should be accompanied by the required instructions for use (Article 13.2)
- The CE marking must appear in any instructions for use (Article 20.3)
- Manufacturers should identify and test measures to safely dispose of the device after use, and these procedures should be explained in the instructions for use (Annex I, clause 14.7)
- Article 23.4 in Annex I provides a list of requirements for the instructions for use of the device

UK Medical Device Regulations 2002

Intended Purpose: the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

Indications for use: 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.

Key Elements of an Intended Purpose

- Structure and Function of the device
- Intended population
- Intended user
- Intended use environment

UK Medical Device Regulations 2002

The **intended purpose statement** should provide with an understanding of

- the appropriate “state of the art”
- product risk level
- and the evidence required to demonstrate the safety of the product.

An inappropriate intended purpose statement can lead to non-compliance with the law and possible safety concerns

ISO 14971:2019

Clause 5.2 makes a specific reference to the **intended use** of a medical device.

5.2 *Intended use* and *reasonably foreseeable misuse*

The *manufacturer* shall document the *intended use* of the particular *medical device* being considered.

The *intended use* should take into account information such as the intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle.

The *manufacturer* shall also document *reasonably foreseeable misuse*.

This documentation shall be maintained in the *risk management file*.

NOTE 1 The use specification (see 3.23 of IEC 62366-1:2015) can be an input to determining the *intended use*.

NOTE 2 See ISO/TR 24971 for factors to consider in determining the *intended use* and for an explanation of *reasonably foreseeable misuse*.

Compliance is checked by inspection of the *risk management file*.

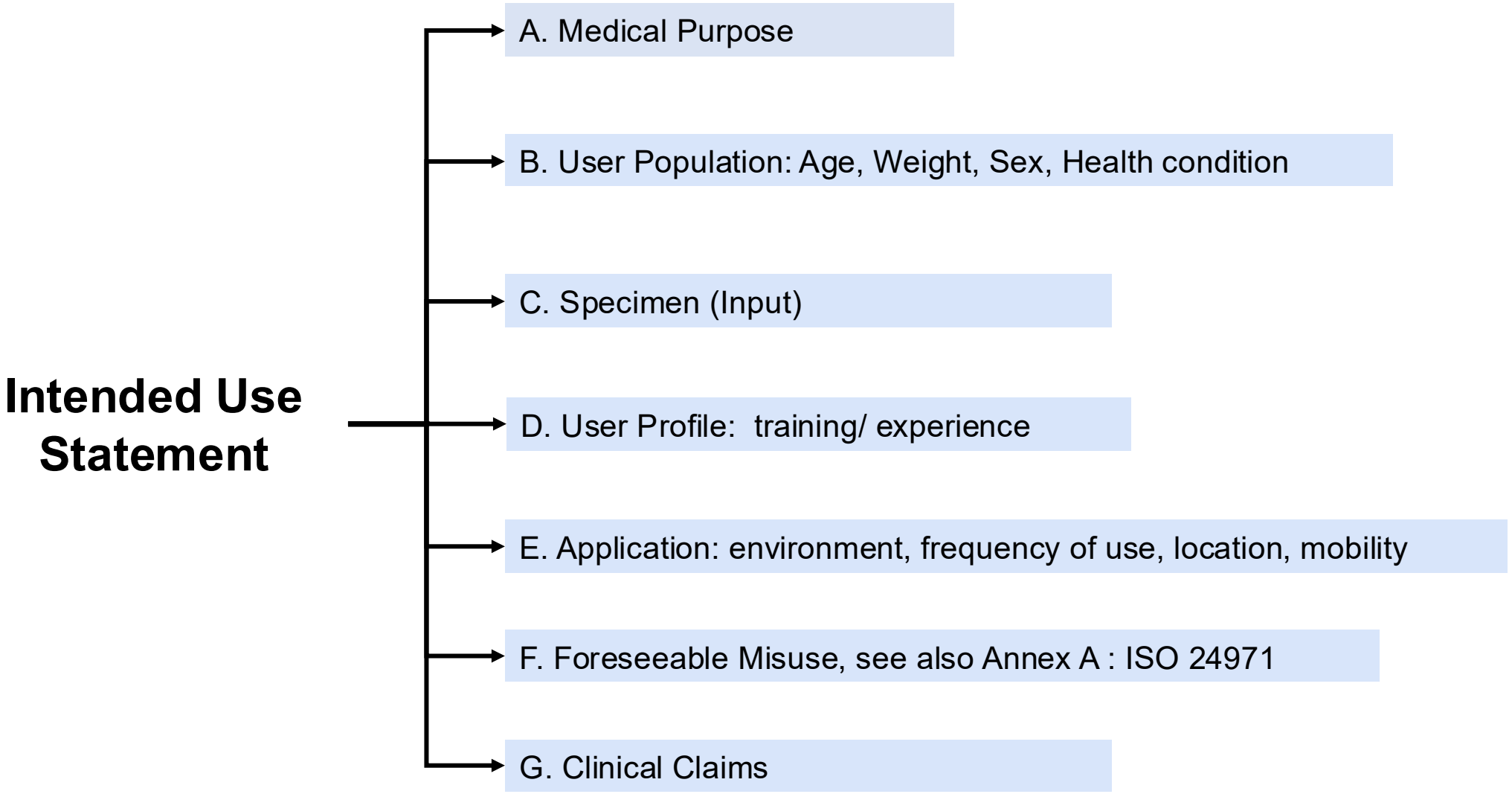
ISO 13485:2016

Intended use

The intended use is mentioned **15 times** in ISO 13485.

Key points include:

- Functional, performance, usability, and safety requirements should be taken into account according to the intended use of the device in the design and development phase (Clause 7.3.3)
- Design and development should be validated to ensure that the device is capable of meeting the requirements of the intended use (Clause 7.3.7)


Intended Use Statement
A. Medical Purpose
B. User Population: Age, Weight, Sex, Health condition
C. Specimen (Input)
D. User Profile: training/ experience
E. Application: environment, frequency of use, location, mobility
F. Foreseeable Misuse, see also Annex A : ISO 24971
G. Clinical Claims

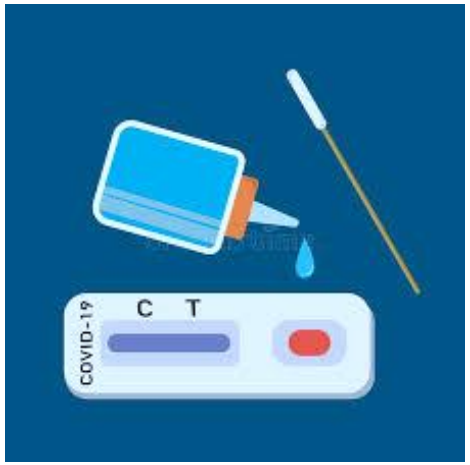
A. Medical Purpose

The Medical Purpose defines that the product is indeed a Medical device, following the definition of the relative jurisdiction for use.

Examples

COVID-19 rapid test kit

Medical Purpose: to allow lay persons to quickly and conveniently test themselves for SARS-CoV-2 infection in a non-clinical setting



Mechanical Ventilator

Medical Purpose: to provide respiratory support or completely replace spontaneous breathing in patients who are unable to maintain adequate ventilation on their own.

B. User Population: Age, Weight, Sex, Health condition

B1. Usability Studies (Validation)

B2. Human Factors

B3. User/ Product Requirements Specification

B4. Clinical Studies/ Evaluation

B5. Product/ Design Validation

COVID-19 rapid test kit

Age: Test kits need to be usable by a wide age range, including elderly individuals and children.	→	Clinical trials should include a broad range of age groups, from children to the elderly, to ensure the test kit is safe and effective across all ages
Weight: Generally less relevant for test kits compared to other medical devices but kit should be easy to use for users of all physical capabilities	→	Testing should include participants with a range of body weights to assess any potential impact on the usability and accuracy of the test.
Sex: The design must be user-friendly for all genders	→	Trials should ensure a balanced representation of sexes to identify any sex-specific issues or variances in test results.
Health Condition: Easy-to-use designs for users with health conditions like arthritis, Clear instructions for users with cognitive impairments.	→	Trails should include participants with various health conditions, particularly those that could affect test use or accuracy, such as cognitive impairments, visual impairments, and chronic illnesses.

Mechanical Ventilator

Age: Must to cater to different age groups. For children, smaller & more precise tidal volume delivery is essential. Adult models need to handle a wider range of lung capacities.	Clinical testing must include diverse age groups to ensure the device is safe and effective across different age ranges.
Weight: The size of the patient impacts the tidal volume and pressure setting. The ventilator needs to accommodate different patient sizes	Trials should include patients across the weight spectrum to ensure that the device can be effectively used in both underweight and obese patients.
Sex: The design should include features to customise settings based on physiological differences, such as lung volume and muscle strength, which can vary between sexes	Sex-based trails to ensure that there are no significant performance disparities between male and female patients
Health Condition: For chronic conditions (eg. ARDS) ventilators must be equipped with advanced modes like high PEEP or pressure support to cater to the specific needs of these conditions.	Trials should involve patients with different health conditions. For example, trials for ARDS patients would test the effectiveness of specific ventilator modes designed for their condition.

C. Specimen (Input)

C1. Design Verification

C2. Specifications

C3. Product requirements

COVID-19 rapid test kit

Specimen input- typically a nasal or throat swab, to detect the presence of SARS-CoV-2 virus.

Design Verification

Accuracy Testing: Conduct trails using nasal and throat swab samples from patients to verify the test's accuracy in detecting SARS-CoV-2.

Reagent and Sample Stability: Perform tests to confirm that reagents and samples remain stable under different conditions, ensuring reliable results

Contamination Control: Validate procedures to prevent contamination during sample collection, processing, and analysis

Specification

Technical Parameters: Define the detection limit, turnaround time, and sample type specifications.

Safety Specifications: Specify the Sterility Assurance Level (SAL) and biocompatibility.

Storage and Stability: Detail the storage conditions for reagents to ensure long-term stability and reliability.

Mechanical Ventilator

Specimen input – Not applicable

Because no biological specimen is required - the mechanical ventilator is used to support the breathing process for patients when their natural breathing is compromised.

D. User Profile: training/experience

D1. Usability/ Human Factors Studies

D2. Instructions for Use

D3. Training

D4. Clinical Evaluation

COVID-19 rapid test kit

Used by laypersons

Usability/Human Factors Studies

Ensure that the COVID-19 rapid test kit can be used correctly and safely by lay persons.

Key Metrics: Ease of use, comprehension of instructions, accuracy of test results, and user confidence

Instructions for Use

Provide clear, concise, and easy-to-understand instructions that guide users through the test process.

Key considerations: Simplified Language, Visual Aids, Highlight Critical Information.

Training

To support users, especially those with no prior experience, in using the test kit. Emphasis on clear, accessible training materials tailored to various literacy levels

Example: Online Tutorials- Create videos demonstrating the entire test process

Clinical Evaluation

Assess the performance of the COVID-19 rapid test kit in real-world settings across different user profiles.

Clinical evaluation data should validate the safety and efficacy of the test kit.

Mechanical Ventilator

Used by healthcare professionals

Usability/Human Factors Studies

Ensure that the ventilator can be operated safely and effectively by healthcare professionals under various conditions.

Includes: User Interface Testing, Stress Testing, Feedback Collection

Instructions for Use

Provide comprehensive and clear guidelines that enable healthcare professionals to use the ventilator effectively.

Key elements: Detailed Manual, Maintenance Instructions, Emergency Protocols

Training

Ensure that healthcare professionals are proficient in using the ventilator and can provide optimal patient care.

Includes: Hands-On Training, Certification Programs, Online Training Module, Simulation Training

Clinical Evaluation

Validate the ventilator's performance, safety, and effectiveness in real clinical settings.

Includes clinical trials in various ICU settings to gather data on the ventilator's performance and patient outcomes.

E. Application: environment, frequency of use, location, mobility

E1. Environment: Validation Tests (Home/ Clinical – Both?)

E2. Frequency of Use: Single Use, Reusable, Sterile/ Non Sterile, Implantable, Non Implantable

E3. Location: Software (Installed/ Cloud based), device to be used at Home or Clinical.

E4. Mobility: Portable/ fixed will it need installation?

COVID-19 rapid test kit

Environment:

It should function effectively in diverse environments

Key Considerations-
Temperature, Humidity, Cleanliness

Frequency of Use

The kit should be designed for single-use

Key Considerations-
Disposable components to prevent cross-contamination and Clear disposal instructions

Location

The rapid test kit can be effectively used in various locations within the home, office or elsewhere

Key Considerations-
Compact and portable design,
Flat and stable test components that can be used on various surfaces such as tables, counters, or laps.

Mobility

The kit should be portable and easy to use for people who need to transport it to different locations

Key Considerations-
Portability, Robustness, Ease of Use on the Go.

Mechanical Ventilator

Environment:

The mechanical ventilator performs reliably under various environmental conditions typical in medical settings.

Key Considerations-
Temperature and Humidity, Electrical Interference, Cleanliness and Sterilisation

Frequency of Use

The mechanical ventilator should handle its expected usage frequency without performance degradation.

Key Considerations-
Durable components that can withstand continuous or frequent use in high-stress environments, Maintenance including routine checks and component replacements.

Location

Suitable for various locations within a healthcare facility.

Key Considerations-
Ventilator's size and shape are suitable for different areas, such as Operating rooms, emergency departments, or intensive care units. Controls and displays are easily accessible to healthcare providers while maintaining patient safety.

Mobility

Installed in the hospital settings - not portable

F. Foreseeable Misuse, see also Annex A : ISO 24971

F1. Will force you to start your Risk Analysis early at least to think of worse case scenario – Death/ Inconvenience?

F2. See also ISO 24971 and answer questions

COVID-19 rapid test kit

Misuse Scenario	Mitigation (to be considered during design and development phase)
Users might use the test kit components incorrectly, such mixing up vials, leading to inaccurate results.	Clearly labelled test components Instructions with clear illustrations
Users might incorrectly collect or handle the sample resulting in insufficient or contaminated samples.	Clear guidance on sample collection and include training materials (like Online Tutorials)
Users might skip steps or misinterpret the instructions, such as not waiting the correct amount of time for the test results to develop	User-friendly design Use clear, unambiguous language and visual aids.
Users might store the test kit in inappropriate conditions, such as extreme temperatures or humidity levels.	Include temperature and humidity indicators or warnings on the packaging. Design packaging to protect the kit from environmental factors.

Mechanical Ventilator

Misuse Scenario	Mitigation (to be considered during design and development phase)
Users might inadvertently set incorrect tidal volumes or pressures, leading to under-ventilation or over-ventilation.	Implement pre-set safety limits and warnings.
Users might incorrectly connect the ventilator tubing, leading to air leaks or inadequate ventilation.	Incorporate visual and audible indicators for proper setup.
Users might ignore or fail to respond to alarms due to misunderstanding or fatigue.	Design distinctive and non-ignorable alarms. Implement a priority system where critical alarms require immediate user acknowledgment.

G. Clinical Claims

G1. Will drive your Clinical evaluation/ studies/ Performance Evaluation/Studies and also your validation needs based on claims

COVID-19 rapid test kit

Claims

- The rapid test kit provides 95% sensitivity and 98% specificity in detecting SARS-CoV-2 infection
- The rapid test kit performs reliably across different age groups and demographics.
- The rapid test kit is stable for 12 months when stored at room temperature.

Clinical Studies

Performance study: Conduct studies in both symptomatic and asymptomatic individuals to measure the test's sensitivity and specificity against a gold standard (e.g., PCR testing).

Population study: Conduct studies involving a diverse range of participants, including different ages, ethnicities, and health conditions

Validation

Validation studies to evaluate the accuracy of test kits under different conditions.

Shelf-Life Validation: Conduct stability studies to confirm that the test kit remains effective and safe over the claimed shelf life

Mechanical Ventilator

Claims

- The ventilator enhances oxygenation in patients with acute respiratory distress syndrome (ARDS)
- The device reduces the incidence of VAP through advanced features like humidification and pressure support
- Highly efficient and easy to set up in emergency situations, reducing the time to initiate ventilation.

Clinical Studies

Conduct a clinical trial with ARDS patients to measure improvement in oxygenation levels.

Implement a study in a hospital setting to track the incidence of VAP in patients using the ventilator compared to those using other devices or standard practices.

Validation

Conduct longitudinal studies to confirm the ventilator's claims under various clinical conditions.

Conduct studies to validate that setup times meet the claims under real-world pressure.

Summary

The **'Intended use'** is the foundation for all decisions and a sufficiently clear intended use is key to meeting various aspects of the medical device regulations effectively.

When clearly defined, the 'Intended Use' will:

- Determine if the product is a "medical device" and help “classify” the device
- Align the Design Process, especially in terms of Usability.
- Ensure that Clinical Development Plan aligns with your Business Development, Regulatory, Device Design & Development, and Quality Assurance plans
- Provide key information for labelling, instructions, clinical evaluation, and technical documentation.
- Promotional materials must be backed by Clinical evidence