# INTERPRETATION GUIDANCE ON ANNEX I, POINTS 11.1 AND 22.2 OF EU REGULATION 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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# CONTENTS



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# 1. INTRODUCTION

## 1.1. Regulation EU 2017/745 of the European Parliament and of the Council on Medical Devices (MDR)

Regulation (EU) 2017/745 on Medical Devices (hereinafter MDR) is a European Regulation on medical devices aimed at ensuring proper operation of the internal market as regards medical devices, taking as its basis a high level of protection of the health of healthcare workers and patients, users and lay persons, and taking into account the interests of small and medium-size enterprises in the healthcare industry[1].

This Regulation came into force on 26 May 2017 and will apply across the European Union from 26 May 2021. The Regulation sets out a goal that all EU countries must achieve and the individual member states decide the way to implement it. The Regulation is a binding legislative act and must be applied in its entirety across the EU when it comes into force.

## 1.2. Importance of the General Safety and Performance Requirements

One key element of the conformity process is the development by the manufacturer of the required technical documentation which shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I of the MDR that are applicable to the device taking into account its intended purpose.

It is very important that there are no gaps in the interpretation of the MDR and in particular of the general safety and performance requirements, to avoid anomalous scenarios which might affect free market competition in Europe, and to avoid situations that might unequally affect the safety of healthcare workers, patients and lay persons who could administer medication using medical devices with needles.

Therefore, the scope of this guidance is to ensure consistency in the implementation and the interpretation of the MDR across Notified Bodies, Member States and manufacturers regarding the requirements defined in Annex 1, points 11.1 and 22.2.

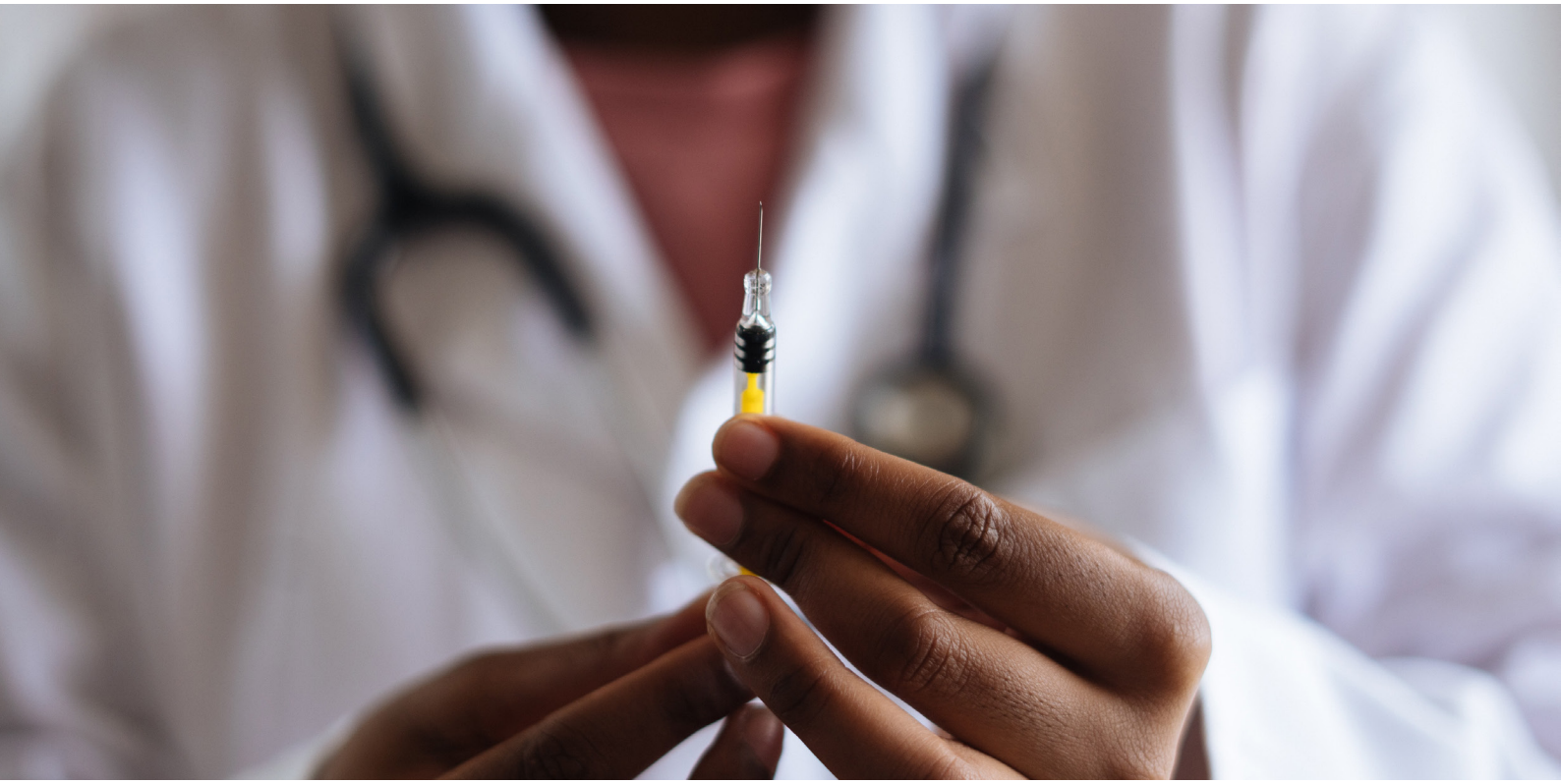
[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC,

## 2. THE MDR AND THE SAFETY OF HEALTHCARE WORKERS, PATIENTS AND LAY PERSONS

The new MDR includes many Articles that require, as far as possible, that medical devices be designed and manufactured in such a way as to ensure the safety of patients, healthcare professionals1 and lay persons.

As regards the safety of healthcare workers, patients and lay persons, the MDR includes two critical points in Annex I, given below:

- *Annex I, Point 11.1: "Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries; allow easy and safe handling; reduce as far as possible any microbial leakage from the device and/or microbial exposure during use; and prevent microbial contamination of the device or its content such as specimens or fluids."*
- *Annex I, Point 22.2: "Devices for use by lay persons shall be designed and manufactured in such a way as to: ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information; reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries; and reduce as far as possible the risk of error by the intended user in the handling of the device."*



## 3. JUSTIFICATION OF THE INTERPRETATION GUIDE FOR POINTS 11.1 AND 22.2 OF APPENDIX 1 OF THE MDR

Unfortunately, both Articles (points 11.1 and 22.2 of Annex I to the MDR) are not sufficiently specific to ensure a consistent interpretation by all European medical devices stakeholders. What is the correct interpretation of the requirement “as far as possible and appropriate”? How and when should it be determined that a medical device was designed to reduce the risk from unintended cuts and pricks as far as possible and appropriate?

The lack of an objective and specific definition in the MDR of how and when a medical device was designed to ensure the safety of healthcare professionals and lay persons poses a serious homogeneity problem for the interpretation of the MDR.

With the current text of points 11.1 and 22.2 of Annex I, the same medical device could be regarded as “non-compliant” with the MDR by one notified body, while another notified body could regard it as compliant with the Regulation. For this reason, the lack of homogeneity in the interpretation of these articles in Annex 1 to the MDR can have the following consequences:

- CE Certification of medical devices that do not guarantee the safety of healthcare workers, patients and lay persons, which is counter to the spirit and purpose of the MDR;
- Co-existence of safe and unsafe devices for healthcare workers, patients and laypersons in the European market;
- Failure to guarantee free competition of medical devices in the European market. As the Certification of the CE mark would depend on the subjective view of the involved notified body, not on objective criteria, a medical device manufacturer could be denied a CE Certification for a medical device by a notified body in one country while another manufacturer of the same device could obtain the CE Certification through a different notified body in another country.

# 4. REGULATIONS IN FORCE REGARDING HEALTHCARE PROFESSIONALS' SAFETY IN EUROPE

## 4.1. Framework Directive 89/391/EEC

This Directive establishes the minimum legal conditions, mandatory for European Union employers, for the application of measures to encourage improvements in the safety and health of workers at work[2]. As with all health and safety legislation, the Directive sets out a hierarchy of measures which creates a systematic approach to managing safety in the workplace by providing a structure to select the most effective control measures to eliminate or reduce the risk of certain hazards that have been identified as being caused by the work process.

The text of this Directive includes article 6 "General obligations on employers". Within the context of their responsibilities, the employer shall take the measures necessary for the safety and health protection of workers, including prevention of occupational risks and provision of information and training, as well as provision of the necessary organisation and systems.

The employer shall implement the preventive measures on the basis of the following general principles of prevention:

- avoiding risks;
- evaluating the risks which cannot be avoided;
- combating the risks at source;
- adapting the work to the individual, especially as regards the design of work places;
- the choice of work equipment and the choice of working and production methods;
- adapting to technical progress;
- replacing the dangerous by the non-dangerous or the less dangerous;
- developing a coherent overall prevention policy which covers technology and organisation of work;
- working conditions;
- giving collective protective measures priority over individual protective measures;
- giving appropriate instructions to the workers.

## 4.2. Directive 2000/54/EC

Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work seeks to protect workers against risks to their health and their safety, as well as to prevent those risks to which they are or might be exposed in their work due to their exposure to biological agents[3].

Article 3 "Determination and assessment of risks" states: "In the case of any activity likely to involve a risk of exposure to biological agents, the nature, degree and duration of workers' exposure must be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken".

In particular, article 6 "Reduction of risks" states that when workers' exposure at work cannot be avoided due to technical-

[2] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work. Official Journal of Luxembourg. No. 183 (29 June 1989).

[3] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work. Official Journal of the European Communities. No. 262 (17 October.2000).

organisational reasons, the type of work activity should be taken into account, as well as the mandatory risk assessment described in Article 3, and on the basis of this the exposure risk should be reduced to the lowest level possible, in order to adequately guarantee the healthcare protection and safety of the workers affected.

## 4.3. Directive 2010/32/EU

Article 3 of Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector clearly establishes that Member States will bring into force the laws, regulations and administrative provisions necessary to comply with this Directive or shall ensure that the social partners have introduced the necessary measures by agreement by 11 May 2013 at the latest[4].

Clause 5 "Risk assessment" explicitly states that risk assessment procedures should be conducted in compliance with Articles 3 and 6 of Directive 2000/54/EC, and Articles 6 and 9 of Directive 89/391/EEC. Clause 5 also states that risk assessment will include all situations where there is injury, blood or other potentially infectious material: risk assessment should also take into account technology, organisation of work, working conditions, level of qualifications, work related psycho-social factors and the influence of factors related to the working environment.

Clause 6 "Elimination, prevention and protection" establishes that workers' exposure must be eliminated by implementing changes in practice and on the basis of the results of the risk assessment, providing medical devices incorporating safety-engineered protection mechanisms.

Clause 8 "Training" of Directive 2010/32/EU obligates the employer to provide exposed workers with adequate training on use of medical devices with an integrated safety mechanism.

Controlling exposures to occupational hazards is the means to protect workers and a hierarchy of controls is used as a means of determining how to implement effective control solutions. The hierarchy of controls in European practice and legislation normally has six levels of control measures, the most effective at the top of the hierarchy. This would involve the following steps:

1. Elimination – removes the cause of the danger
2. Substitution – controls the hazard by replacing it
3. Isolation – separates the hazard from the people at risk
4. Engineering – removes hazard or creates a barrier between user and risk
5. Administrative – administrative controls are training, design and procedural
6. Personal Protective Equipment (PPE) – equipment that prevents risks

To conclude, the European regulations in force in the form of "Directives" clearly establish that medical devices with a safety mechanism are the most suitable devices, as far as possible, to guarantee the protection of healthcare workers, patients and lay persons against biological risk due to unintended pricks or cuts, such as needle stick injuries.

[4] Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU. Official Journal of the European Union. No. 134 (1 June 2010).

# 5. KEY FACTORS TO CONSIDER IN THE INTERPRETATION OF POINTS 11.1 AND 22.2 OF ANNEX 1 OF THE MDR

The only way to ensure a homogeneous interpretation of points 11.1 and 22.2 of Annex I to the MDR is the inclusion of the concept of "medical devices incorporating safety-engineered protection mechanisms".

## 5.1. Key factor 1

Medical devices that include a built-in safety mechanism are designed as the devices to prevent biological accidents "as far as possible and appropriate". Of course, this does not guarantee the prevention of all accidents, as it depends on the previous training received by the user, the proper use by the healthcare professional or lay person of the medical device and accidents occurring during the use of the device for its original purpose (e.g . due to a movement of the patient) before the safety mechanism is activated. Since the MDR is specifically aimed at manufacturers of medical devices, the safety mechanism must be integrated in the medical device, it should never be an added accessory.

## 5.2. Key factor 2

Medical devices that include a built-in safety mechanism means that the protective safety features have to be integrated in the medical device directly delivered to the end-user, and never be an added accessory. If the safety mechanism is not integrated into the final device then the design of the final device cannot be considered to prevent pricks and cuts "as far as possible and appropriate".

The MDR is aimed at the manufacturers of medical devices to ensure that they are designed and manufactured products to ensure the safety of healthcare professionals and third parties, not healthcare systems in themselves. For this reason, unless the safety-engineered protection mechanism is integrated into the final product delivered to final users, it cannot be regarded as complying with the MDR.

## 5.3. Key factor 3

Directive 2010/32/EC of 10 May 2010, implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector specifies: "Eliminating the unnecessary use of sharps by implementing changes in practice and, on the basis of the results of the risk assessment, providing medical devices incorporating safety-engineered protection mechanisms".

## 5.4. Key factor 4

In order to prevent monopolies in the European market, it is mandatory that the built-in safety mechanism for each intended use of invasive medical device (syringes, needles, catheters, insulin pens, etc.) is already available in the European market from at least two manufacturers. This will prevent potential monopolies in Europe.

To this end, it is very important that the "EUDAMED" European Medical Device database specifies whether the existing CE marked invasive medical devices incorporate safety-engineered protection mechanisms. If the full EUDAMED database is not available at the implementation deadline for the MDR of 26 May 2021, a transition solution will be required. One potential solution would be that Notified Bodies communicate to the European Commission the list of invasive devices classified by intended use, incorporating safety engineered protection mechanisms which have been CE certified. Then, the European Commission would issue this list on a quarterly basis in the Official Journal of the European Union.

## 5.5. Key factor 5

It is important to highlight the need to include some exceptions to this interpretation guide in order to ensure the safety of healthcare workers, patients and lay persons, as well as to take into account the transition required from the current Medical Devices Directive to the new MDR applicable by 26 May 2021, when the MDR will apply across the European Union.

The exceptions to this guide identified are the following:

- On the basis of Directive 93/42/EC and its later amendments, medical devices that are currently available in the market can still be placed on the market until the date of expiry of their current "EC certificate", or at the latest until the end of the transition period (26 May 2024);
- Medical devices the intended use of which is "self-injection" by patients. In this case, the use of sharps containers for the disposal of medical devices is critical to protect patients´ environment and safety;
- Devices for medication loading and transfer, where a blunt tip design would be required;
- Invasive products whose intended use is to access small spaces, particularly ear, nose and throat and ophthalmologic procedures, and where safety mechanisms may prevent the proper intended operation of the device and increase the risk for patients vs. the benefit of the intended use of the device.

# 6. GENERAL REQUIREMENTS FOR A MEDICAL DEVICE WITH AN INTEGRATED SAFETY MECHANISM

The most appropriate and best technical requirements to be met by a medical device to guarantee, in the best way possible, the safety of healthcare workers, patients and lay persons who use it are established in EN ISO 23908-2013 "Sharps injury protection. Requirements and test methods. Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling".

These general requirements are:

**Requirement 1:** Activation of the sharps protection feature shall permit the user's hand(s) to remain behind the exposed contaminated sharp. Safety features may be operated either actively or passively. If active operation is required, one-handed operation is recommended.

**Requirement 2:** Once in safe mode, the safety feature shall:

a) Resist forces so as to prevent unintended exposure to the sharps

b) Minimize the risk of accidental access to the sharp using a risk-based approach in accordance with ISO 14971, the manufacturer shall determine appropriate minimum overriding forces.

**Requirement 3:** Activation/safe mode shall be communicated to the user in a clear and unmistakable manner by either visual, tactile and/or audible means.

It is very important to point out that other international bodies with scientific-technical evidence available have applied the same general requirements as the INSSBT, such as NIOSH (the US National Institute of Occupational Safety and Health), and CDC (the US Center for Disease Control and Prevention).

[5] EN-ISO 23908: 2013 "Sharps injury protection -Requirements and test methods-Sharps protection features for single-use hypodermic needles introducers for catheters and needles used for blood sampling"

[6] Preventing exposures to blood borne pathogens among paramedics. DHHS (NIOSH) publication 2010-139 [Internet]. Atlanta: National Institute for Occupational Safety and Health (NIOSH); 2010. [Cited 2018 May 30]. Available at: https://www.cdc.gov/niosh/docs/wp-solutions/2010-139/pdfs/2010-139.pdf

[7] Workbook for Designing, Implementing and Evaluating a Sharps Injury Prevention Program [Internet]. Centers for Disease Control and Prevention (CDC); 2008. [Cited 2018 May 30]. Available at: https://www.cdc.gov/sharpssafety/pdf/sharpsworkbook_2008.pdf

# 7. INTERPRETATION OF POINTS 11.1 AND 22.2 OF ANNEX 1 OF THE MDR

After examining all the points above with scientific evidence, for points 11.1 and 22. 2 of Annex I to Regulation EU 2017/745 of the European Parliament and of the Council on Medical Devices, which state respectively that:

"Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries"; and "Devices for use by lay persons shall be designed and manufactured in such a way as to reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries";

the appropriate and final interpretation is as follows:

- Invasive products delivered to end-users whose intended use is the administration and/or extraction of body/blood fluids and/or medicines that may result in cuts and pricks and whose design does not include a built-in safety mechanism means that those products whose design does not include protective safety features integrated in the product will be regarded as non- compliant with the safety and operating requirement above, and therefore may not be CE Certified and therefore CE marked, provided that there are products with the same intended use in the market which have been classified as compliant with this Regulation and which incorporate such safety mechanisms.
- Built-in safety mechanisms have to meet the following main requirements:
  - The safety mechanism must be integrated in the needle or in the sharp instrument, and should never be an added accessory;
  - Activation of the sharps protection feature shall permit the user's hand(s) to remain behind the exposed contaminated sharp. Safety features may be operated either actively or passively. If active operation is required, one-handed operation is recommended;
  - The safety mechanism must protect against all the sharps in the device;
  - Activation/safe mode shall be communicated to the user in a clear and unmistakable manner by either visual, tactile and/or audible means;
  - Once in safe mode, the safety feature shall:
    A. resist forces so as to prevent unintended exposure to the sharps; and
    B. minimise the risk of accidental access to the sharp;
  - The safety feature will continue to provide protection even after it is discarded;
  - The medical device works in a reliable way and in any size;
  - The medical device is practical and easy to use;
  - The medical device makes it possible to treat patients in an effective and safe way.
- CE marked invasive products with a built-in safety mechanisms satisfying points 11.1 and 22. 2 of the General Safety and Performance Requirements will be clearly identified in the EUDAMED database. The certificate of products with the same intended use and whose design does not incorporate a safety mechanism shall not be renewed by the Notified Body when their CE certificate, issued as per the Medical Devices Regulation EU 2017/745, has expired and when devices with built-in safety mechanisms are available from a minimum of 2 manufacturers.

**Exceptions:**

- On the basis of Directive 93/42/EC and its later amendments, medical devices that are currently available in the market can still be placed on the market until the date of expiry of their current “EC certificate”, or at the latest until the end of the transition period (26 May 2024).
- Medical devices the intended use of which is “self-injection” by patients. In this case the use of sharps containers for medical devices disposal is critical to protect patients´ environment and safety.
- Devices for medication loading and transfer, where a blunt tip design would be required.
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