



CONSEJO GENERAL DE ENFERMERÍA  
DE ESPAÑA

**Presentation by Dr Jose Luis Cobos,  
Spanish General Council of Nursing  
Webinar on preventing sharps injuries, the MDR and the standard on  
safety mechanisms in medical devices, 15 June 2021**



# SURVEY ON SHARPS INJURIES IN SPAIN AND THE SHARPS DIRECTIVE



CONSEJO GENERAL DE ENFERMERÍA  
DE ESPAÑA

## **The Spanish General Nursing Council undertook a study to look at compliance with the Sharps Directive 2010/32/EU and implementation of safety measures in Spanish healthcare facilities**

The study examined the situation in 144 healthcare facilities (71 hospitals and 73 healthcare centres), with the cooperation of 120 surveillance nurses

- 95% of Spanish healthcare facilities had experienced sharps injuries and risk assessments were not carried out in 9.7% of facilities examined
- More needle free devices and safety devices were provided in hospitals than healthcare centres
- 18.8% of staff were not trained to use a medical device with a safety mechanism
- Safety devices were most often available for blood collection and in catheters but least frequently in pre-loaded syringes, scalpels and insulin pens

The study concluded that safety devices were the main preventive measure put in place to protect nurses in Spain, that the Sharps Directive was not being implemented in all Spanish facilities and that a European Biosafety Observatory should be established to collect data and information on workplace injuries.

# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS



CONSEJO GENERAL DE ENFERMERÍA  
DE ESPAÑA

**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC (MDR), Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC**

- The Regulation (EU) 2017/745 on Medical Devices is a European Regulation 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.
- One key element 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.

# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

- 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 invasive medical devices.



- 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 professionals and lay persons.

# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

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.”*

# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

## Lack of homogeneity in the interpretation

- 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 the 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?

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.

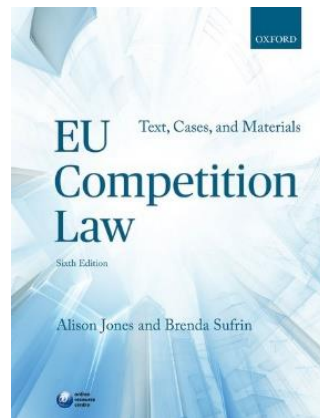


# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

## Consequences of lack of homogeneity in the interpretation

- **No guarantee of safety** for healthcare workers, patients and lay persons :
  - Medical devices with CE mark that are not safe
  - Co-existence of safe and unsafe devices in the European market for the same intended use.
- **No free competition in Europe** of medical devices manufacturers 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.



To solve this significant issue, **one standard** 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. **is required.**

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

The Spanish General Council of Nursing drafted interpretation guidance which, following consultation with a number of bodies, was published, together with the European Biosafety Network, on 28 April 2021.

- 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.
- The guidance is designed to be adopted and/or adapted for publication by the Medical Devices Coordination Group (MDCG) following the full applicability of the MDR on 26 May 2021, but also to inform the development of a new standard and a possible technical report for updating the standard on safety mechanisms in medical devices

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

April 2021

Authors

Rafael Jesús López Suárez, PhD, MSN, RN  
José Luis Cobos Serrano, PhD, MSN, RN



# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

## Objective criteria

- 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 one objective criteria:

*“medical devices incorporating safety-engineered protection mechanisms”*

- The European regulations in force in the form of Directives clearly establish that medical devices with a built-in safety mechanism are the most suitable solution 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.

Objective criteria:  
Safety –engineered mechanism



# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

## Guidelines and Standard required

- One set of guidelines and a standard are required 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.
- The stakeholders in the standardisation working group should include input from representatives from healthcare and other economic operators, medical device industry, healthcare professionals, patients and unions and hospitals.
- The MDCG and the sub group on standards should help with providing greater clarity and guidance to Notified Bodies, Member States and manufacturers now the MDR fully applies.

# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

The guidelines and Standard should be based on EN ISO 23908 : 2013

## **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”**

- 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”.

# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY- ENGINEERED MECHANISMS

## **Draft Commission decision for consultation in regard to the standardisation request in support of Regulation (EU) 2017/745 and 746 of the European Parliament and of the Council**

The draft standardisation request in Table 1 of Annex I among the “existing harmonised standards to be revised” and in Annex III, Part B, among the “Requirements for certain specific standards listed in Annexes I and II” includes:

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

2.3. Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (EN ISO 23908:2013)

The existing standard EN ISO 23908:2013 shall be modified by describing technical solutions for safety-engineered mechanisms to be applied in design and manufacture of devices to ensure compliance with points 11.1 and 22.2 of Chapter II of Annex I to Regulation (EU) 2017/745. The standard shall apply to devices which are intended to be used for administration and/or extraction of body/blood fluids and/or medicinal substances.

# REGULATIONS ON MEDICAL DEVICES INCORPORATING SAFETY-ENGINEERED MECHANISMS

## Next steps

The deadline for the draft standard commissioned by the European Commission is 27 May 2024 and it should take 2-3 years for the drafting, technical work and editing to produce a final standard.

- Working Group 8 of ISO/TC 84 (alongside CEN/TC 205) has agreed in principle to undertake the new standard over the next year in parallel with, and in anticipation of, the development of the new standard.
- A proposal for a new work item will be submitted in due course to the secretariat of ISO/TC 84/WG8 and CEN/TC 205.
- The MDCG should adopt guidance based on the interpretation guidance drafted by the Spanish General Council of Nursing

# PREVENTING SHARPS INJURIES

## Conclusions

Sharps injuries will be eliminated and health workers and patients will be protected from deadly diseases by:

- consistent interpretation and universal implementation of the existing Sharps Directive and Medical Devices Regulation;
- introducing EU wide surveillance and the development of a permanent observatory to deliver detailed and updated information and data on sharps injuries and other accidents;
- comprehensive use of safety devices and a new standard on safety mechanisms in medical devices.