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Code of Practice on Standardisation

Barry Cox – NSAI Standard development

7th Sept 2023.

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The HSbooster.eu has received funding from the European Union's Horizon Europe Framework Programme (HORIZON) - under grant agreement no 101058391.

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What is the Code of Practice on Standardisation for Researchers ?

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In Brief

"Standards bridge the gap between research and market up-take. Together with stakeholders we have developed the code of practice to ensure that research and innovation results create marketable solutions and respond to societal challenges"

Mariya Gabriel, Commissioner for Innovation, Research, Culture, Education and Youth

Higher education institutions and Research & Innovation organizations

Project partners

Policy and stakeholders

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Higher education institutions and private and public research and innovation organisations

- Develop a standardisation policy,
- Consider standardisation activities in the career development plans
- Provide for education and training on standardization
- Make Technology Transfer Offices fit for standardization
- Develop an Indicator and Evaluation System

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Project Partners

- Analyze the existing standards landscape
- Develop a common consortium strategic position on standardization
- Involve experienced partners to make standards a tangible part of the project
- Invest in stakeholder engagement
- Have realistic outputs, outcomes and impacts
- Ensure sustainability beyond the project duration

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Policy and stakeholders

- Member States to promote standardization as means of knowledge valorization
- Standards Development Organizations to develop their service portfolios for R&I actors
- Member States to use national support structures for R&I projects

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Why Develop a Code of Practice for Researchers?

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CE Marking

EC DECLARATION OF CONFORMITY

Number:	PSEN0030
Version:	02

LINET

1. Product - instrument Type / Model:

Electrically operated hospital bed with scales – ***Eleganza 5 / 1GE5***

2. Name and address of the manufacturer:

Commercial name	**LINET spol. s r.o.**
Registered address	Želevčice 5, 274 01 Slaný, Czech Republic
Reg. No.	00507814
Telephone	+420 312 576 111
Fax	+420 312 522 668

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of declaration:

Product:	**Eleganza 5 with scales (WS17)**
Description and function designation:	Electrically operated hospital bed with scales, intended for use in intensive and acute care. This EC conformity declaration also covers all applicable accessories.
Classification of the product as the medical device:	**Class** I non sterile, with measuring function, according to annex IX of Government Order No.54/2015 Coll. (MDD 93/42/EEC) – rule 12

5. The object of the declaration described above is in conformity with the relevant Union harmonization legislation:

- Act No. 268/2014 Coll., on Medical Devices (Directive 93/42/EEC)
- Act No. 350/2011 Coll., on chemical substances and mixtures (Regulation (EC) No 1907/2006)
- Government Order No.54/2015 Coll., with is specifies technical requirements for medical devices (Directive 93/42/EEC)
- Applicable requirements of Government Order No.176/2008 Coll., on machinery devices (Directive 2006/42/EC)
- Government Order No.481/2012 Coll., on the restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)
- Government Order No.121/2016 Coll., on non-automatic weighing instruments (Directive 2014/31/EU)

6. References to the relevant harmonized standards used or references to the other technical specifications in relation to which conformity is declared:

EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010, EN 60601-2-52:2010, EN ISO 14971:2012, EN 45501:2015, EN ISO 10993-5:2009 and EN ISO 10993-10:2013.

ISO/TC 215

Health informatics

SUSTAINABLE DEVELOPMENT GOALS

This committee contributes with 241 standards to the following Sustainable Development Goals:

1 2 3 4 5 8 9 10 11 12 13 16

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The 2023 annual Union work programme for European standardisation

Actions for the development and revision of European standards or European standardisation deliverables supporting the internal market for services and products				
Ref	**Title**	**Reference**	**European standards/European standardisation deliverables**	**Specific objectives and policies for European standards/European standardisation deliverables**
70	Medical devices and in vitro diagnostic medical devices	Regulation (EU) 2017/745 on Medical Devices (MDR) Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)	Revise existing standards and develop new European standards for design and manufacturing of: – medical devices covered by Regulation (EU) 2017/745 (MDR) – in vitro diagnostic medical devices covered by Regulation (EU) 2017/746 (IVDR). The standards will apply to design and manufacturing, risk management and obligations on economic operators and sponsors, including those relating to: – quality management systems – risk management – clinical investigations and performance studies – clinical evaluation.	Ensuring the smooth functioning of the single market as regards medical devices by setting high standards of quality and safety for medical devices and in vitro diagnostic medical devices. These should meet common safety concerns as regards such products, thus ensuring a high level of health protection and safety for patients, users and other people.

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Resources for your Standardization Journey

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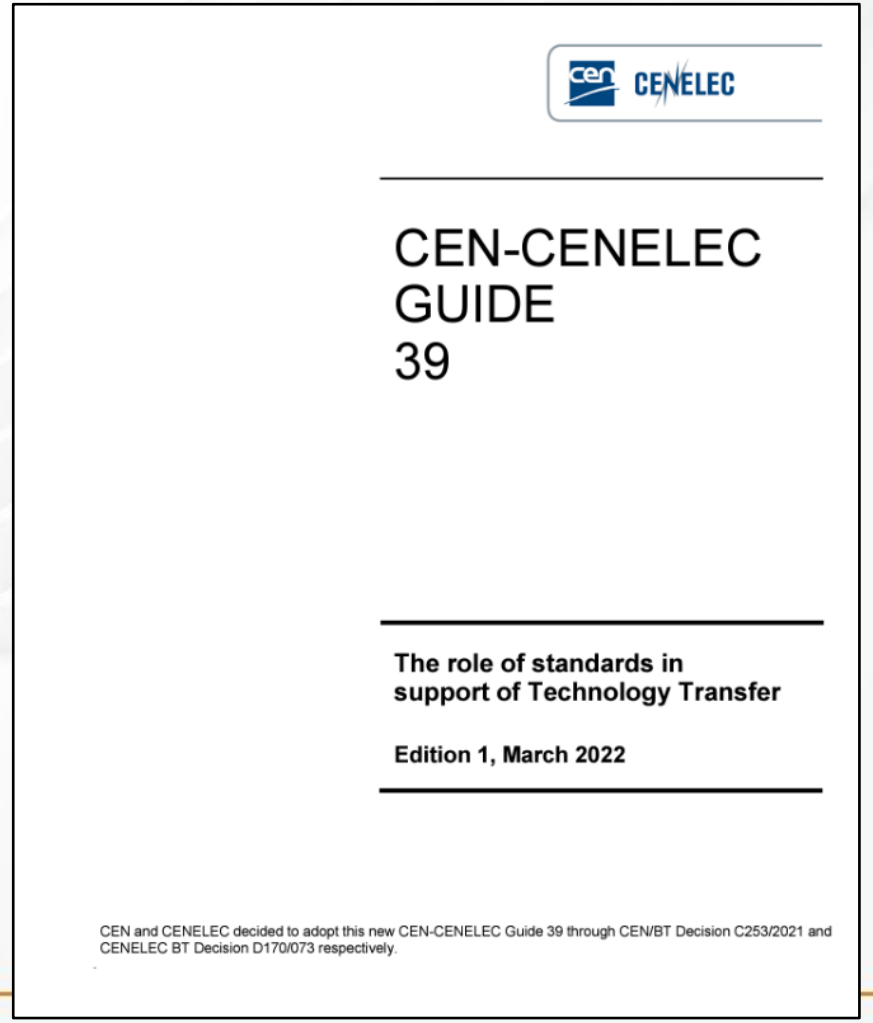
Make Technology Transfer Offices fit for standardization

In practice:

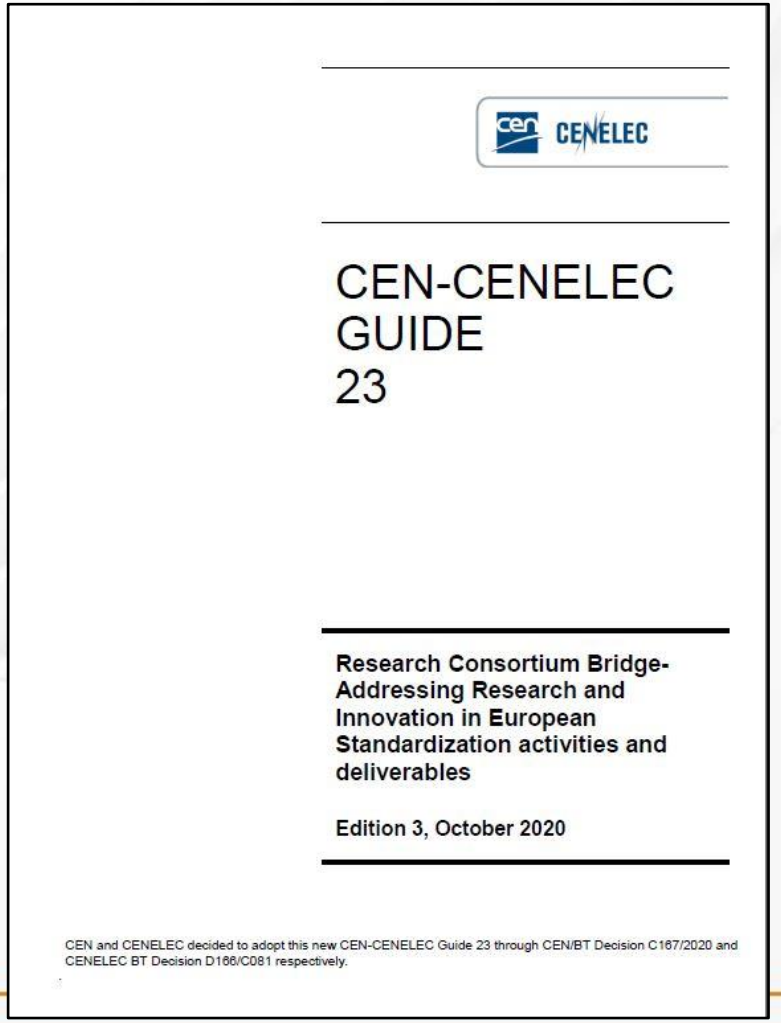
- **CEN-CENELEC Guide 39** '*The role of standards in support of* ***Technology Transfer***' can support raising awareness on the benefits of standardization in supporting technology transfer process



Addressing Research and Innovation in European Standardization activities and deliverables

In practice:

- **CEN-CENELEC Guide 23** *'Research Consortium Bridge- Addressing* ***Research and Innovation in European Standardization activities and deliverables****'* can strengthen the competitiveness of European industry as well as Europe's society as a whole through a strong relationship between research, innovation and standardization.


CEN CENELEC

CEN-CENELEC GUIDE 23

Research Consortium Bridge- Addressing Research and Innovation in European Standardization activities and deliverables

Edition 3, October 2020

CEN and CENELEC decided to adopt this new CEN-CENELEC Guide 23 through CEN/BT Decision C167/2020 and CENELEC BT Decision D166/C081 respectively.

CEN Workshop Agreements

- This CEN Workshop Agreement (CWA) aims to cover limitations in existing practices and implement a good practice guide for obtaining user consent for personal health information

CWA 17933:2023 -- Digital health innovations - Good practice guide for obtaining consent for the use of personal health information for research and innovations

European Project Liaison

- Its standard practice the **International Organisation of Standardisation (ISO) to approved Horizon 2020/Horizon Europe project candidacy for a Liaison Category C**
- The project is considered an external organisation according to ISO Rules and as Category C liaison organisation has the right to participate as full member in a working group, maintenance team or project team but not as project leader or convenor

Standards Deliverables as part of European Projects

- **UNICOM**

Up-scaling the global univocal identification of medicines

WP 1 IDMP-related standards and terminologies - D1.1: Gap Analysis of Existing and Need for New Standards and Profiles

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Take away

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Standards?

Standards are part of your industry

You can see Standards as they develop

You can be part of the Standard as it develops

National Standard Bodies are here to help you

THANKS!

GET IN TOUCH WITH US!

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