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Sledljivost medicinskih pripomočkov, omogočena z enotno identifikacijo pripomočka (UDI)

Medical device traceability enabled by unique device identification (UDI)

Rückverfolgbarkeit von Medizinprodukten durch Unique Device Identification (UDI)

Traçabilité des dispositifs médicaux à l'aide de l'identification unique des dispositifs (UDI)

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This Technical Report was approved by CEN on 24 May 2014. It has been drawn up by the Technical Committee CEN/CLC/TC 3.

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Foreword

This document (CEN/CLC/TR 14060:2014) has been prepared by Technical Committee CEN-CENELEC/TC 3 “Quality management and corresponding general aspects for medical devices”, the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes CR 14060:2000.

The COMMISSION RECOMMENDATION 2013/172/EU of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union should be used as common guideline and was used in the developing this document.

Introduction

Benefits of Tracking and Tracing.

Traceability of medical devices throughout the whole supply chain (finished goods to patient) contributes to patient safety and safety of users by facilitating:

a) a reduction of medical errors linked to misuse of the device;

b) improved incident reporting;

c) efficient recalls and other field safety corrective actions (FSCA);

d) efficient post market actions e.g. by manufacturers and competent authorities;

e) supply chain efficiencies, including better distribution control, stock management and reimbursement;

f) detection of counterfeit products when they enter the supply chain, and

g) compliance to environmental regulations.

The current regulatory framework for medical devices does not include specific provisions on traceability. However, the proposal from the European Commission for a regulation of the European Parliament and of the Council on medical devices[1], include provisions on traceability of medical devices and *in vitro* diagnostic medical devices, in order to improve patient health and safety.

This follows significant efforts that have been and are continuing to be made at international level towards a globally harmonized approach to traceability and to establish a globally accepted unique device identification (UDI) system for medical devices (see Annex A).

Fundamental to establishing an effective medical device traceability system harmonized at a European level is implementation of UDI and the sharing of key information between stakeholders.

This document is a high level executive summary of traceability of medical devices. Its target audience is any and all stakeholders participating in the medical device supply chain, from raw materials to the patient. It is not intended to provide detailed information for full implementation of traceability systems.

[1] The proposal from the European Commission for a regulation of the European Parliament and of the Council on medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 adopted on 26 September 2012, and the proposal from the European Commission for a regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices adopted on 26 September 2012.

1 Scope

This Technical Report identifies key elements needed for a European system that would provide traceability to the individual patient level.

This Technical Report applies to medical devices, active implantable medical devices and *in vitro* diagnostic medical devices, including their accessories. Other devices which are custom-made or intended for clinical investigations and those *in vitro* diagnostic medical devices which are manufactured in health institutions and for performance evaluation are out of the scope of this document.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
traceability
ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration

[SOURCE: EN ISO 9001:2008]

Note 1 to entry: The term 'traceability' as defined in 2013/172/EU is: the ability to trace the history, application or location of that which is under consideration. The reason for not using the definition of 2013/172/EU for the purposes of this document is that it only covers the 'trace' part of traceability and not the 'track' part.

Note 2 to entry: The term 'traceability' defined by GS1 is: 'The ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration'. GS1 is an international not-for-profit association dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors.

2.2
medical device
any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[SOURCE: Directive 93/42/EEC]

2.3
active implantable medical device
any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

[SOURCE: Directive 90/385/EEC]

2.4
***in vitro* diagnostic medical device**
any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

— concerning a physiological or pathological state, or

— concerning a congenital abnormality, or

— to determine the safety and compatibility with potential recipients, or

— to monitor therapeutic measures

Note 1 to entry: Specimen receptacles are considered to be *in vitro* diagnostic medical devices. 'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Note 2 to entry: Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

[SOURCE: Directive 98/79/EC]

2.5
unique device identification (UDI)
data coding system that is created through an internationally accepted device identification and coding standard and allows the unambiguous identification of specific medical devices on the market. The UDI comprises the device identifier and production identifier

[SOURCE: Recommendation 2013/172/EU]

2.6
device identifier
unique identification specific to a manufacturer and a device model

[SOURCE: Recommendation 2013/172/EU]

2.7
production identifier
unique identification that identifies data related to the unit of device production

[SOURCE: Recommendation 2013/172/EU]

2.8
UDI carrier
way in which the unique device identification is conveyed by means of the Automatic Identification and Data Capture (AIDC) and, if applicable, its human readable interpretation (HRI)

[SOURCE: Recommendation 2013/172/EU]

2.9
UDI electronic system
central repository/database storing device identifier codes and related/associated identifying information of specific devices placed on the Union market

[SOURCE: Recommendation 2013/172/EU]

Note 1 to entry: There may be national databases that feed the central EU database.

2.10
human readable interpretation (HRI)
legible format of the data characters encoded in the AIDC symbol

[SOURCE: Recommendation 2013/172/EU]

2.11
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

[SOURCE: Directive 93/42/EEC]

2.12
authorised representative
any natural or legal person established within the Union who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under the relevant Community legislation

[SOURCE: Directive 93/42/EEC]

2.13
importer
any natural or legal person established within the Union who places a device from a third country on the Union market

[SOURCE: Regulation No 765/2008]

2.14
distributor
any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market

[SOURCE: Regulation No 765/2008]

2.15
user
person, either professional or lay, who uses a device

[SOURCE: Recommendation 2013/172/EU]