Irish Standard Recommendation
S.R. CEN/CLC/TR 14060:2014

Medical device traceability enabled by unique device identification (UDI)

S.R. CEN/CLC/TR 14060:2014

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Medical device traceability enabled by unique device identification (UDI)

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

Rückverfolgbarkeit von Medizinprodukten durch Unique Device Identification (UDI)

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.