

English version

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 devices¹, 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]