Activity 1.5 ME

Work in new areas

November 23-27 2015

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Medical device

A medical device is "an instrument, apparatus, implement, machine, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

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UNI EN ISO 13485:2014

CEE DIRECTIVES

UNI CEN ISO/TR 14969

UNI EN ISO 9001:2008

ISO 10012

AMBIENCE HEALTH AND SECURITY FINANCE

APPLICATION GUIDELINE

NON INCLUDED REQUIREMENTS

Supporting standards

Foundations and terminology:

UNI EN ISO 9000

Audit guideline

UNI EN ISO 19011

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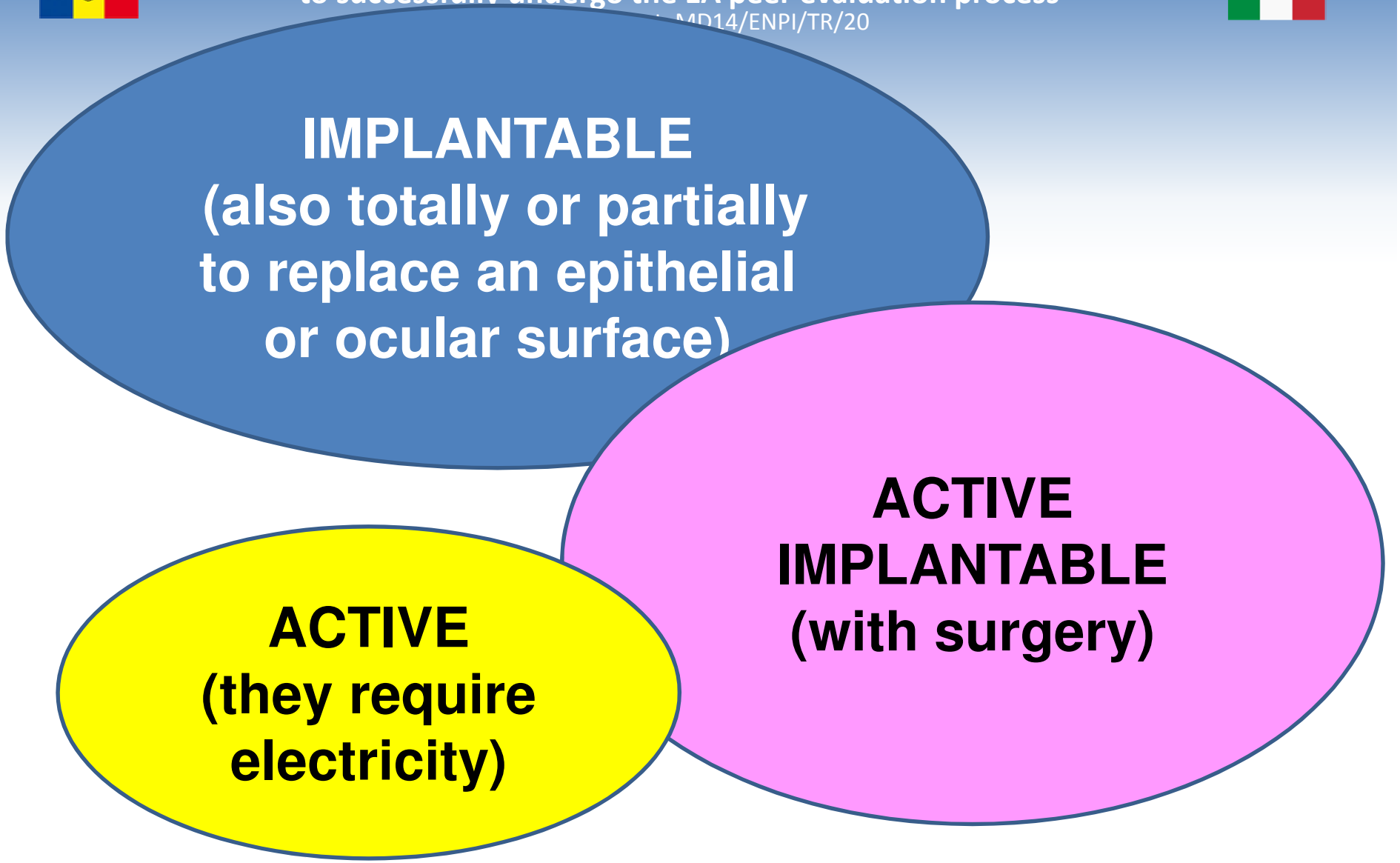

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Manufacturer

It will be the manufacturer, as laid down in the Directive, it has to ensure that his product meets the essential requirements of safety and efficacy that apply to it, documenting the process through the preparation of a technical document which includes documentation relating to design, risk management, the manufacture of products, to any test reports, labels and instructions for use, in clinical data confirming the effectiveness device and instructions on procedures for monitoring during post-marketing experience (post-marketing), including traceability, the alerts issued by accidents and the withdrawal from the market.

Production

You can fit all requirements of UNI EN ISO 9001 (information describing the characteristics of the product, documented instructions for the costruction, use of suitable equipment and also) as the specific requirements of UNI EN ISO 13485:

-Methods of labeling and packaging;
-Retention of record of the lots (including one medical device may be a lot);
-Documented requirements for cleanliness and product documentation.

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Declaration of conformity

Document by which a manufacturer ensures and declares that its products meet the applicable provisions of the directive reference. In a system that liability strongly the manufacturer, the declaration of conformity is not a document but a formal assumption of responsibility necessary for the CE marking of the product and its marketing. The content of the EC declaration of conformity are laid down directive by directive, according to the product concerned.

CE certification

Document by which a subject of third party (Notified Body) certifies that it has carried out a process of evaluation of the compliance of a medical device to the relevant provisions of the Directive reference. Later it will learn in detail the structure and content of the various types of certificates issued by Notified Bodies.

Notified Bodies are public or private entities authorized to perform certification activities, in the context of a specific Directive, the Competent Authorities of the countries in which they are located. A manufacturer may request the required certification to a notified body authorized by any competent authority. The certification allows the CE marking of the product and its free movement in the EU countries..

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MONITORING

MONITORING PROCESS

APPROPRIATE METHODS TO MONITOR AND MEASURE PROCESSES TO PROVIDE EVIDENCE OF THE REACHED RESULTS

DEVICES MONITORING

THE DEVICE CAN'T BE RELEASED UNTIL EVERY REQUIREMENT EXPECTED FROM THE OFFER ARE NOT SATISFIED

APPROPRIATE METHODS TO MONITOR AND MEASURE DEVICES' FEATURES. THE RELEASE MUST NOT BE MADE UNTIL RESULTS WILL NOT SATISFACTORILY COMPLETED

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validation

All productive processes, whose final result cannot be checked from successive monitoring activities must be validated.

The sw used must be validated before the first use and during any modification

All activities must be recorded and recordings must be preserved

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Vigilance

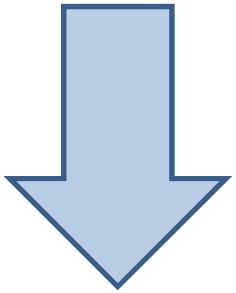
- Directive 90/385/CEE 20 June 1990, art. 8
(Update Directive 2007/47/CEE September 2007)
- Directive 93/42/CEE 14 June 1993, art. 10
(Update Directive 2007/47/CEE del September2007)
- MEDDEV 2,12-1 Rev.6 – December 2009
Guidelines on a medical devices vigilance system

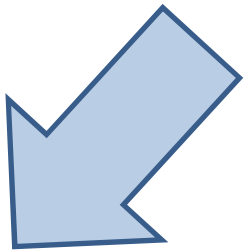
Monitoring

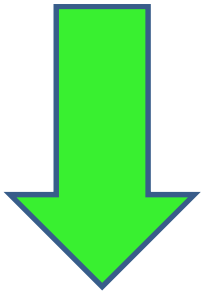
The Ministry of Health is responsible for monitoring the institutional device market and for this purpose, since 2002, are planned and organized inspection visits to companies engaged in the business of manufacturing and distribution of medical devices, including manufacturers of medical devices

Installation activities

Assistance activities







The management arrangements should be documented and records kept of the work completed

Repair maintenance

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The new approach

- 90/385 / EEC on active implantable medical devices
- 93/42 / EEC on roll in general
- 98/34 / EC governing the diagnostic medical devices in vitro

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AIM OF THE REGULATION

Facilitate the harmonization between the regulatory requirements of the medical device for the management systems of quality

APPLICATION

Every organization that produce medical devices regardless of their size

Why?

Until 1985 the Community institutions had tried to reach the goal of a single market within the European Community directives through harmonization of national legislation, which aimed to establish all technical aspects of the products from time to time considered and imposed on Member States to abandon their own particular discipline conforming to the stability of the Community. This system (used for example in the field of drugs and to regulate various aspects of the food industry), though was not problematic, because the setting of technical requirements of detail required long lead times, which appeared incompatible with the ambitious goals it had set the Community . With a resolution of 7 May 1985 (85 / C 136/01), the Council approved, thus supporting a new approach to technical harmonization, based on the approval of provisions applicable to sectors and large families of products and types of risk.

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Clinical tests

Device manufacturer or his authorized representative, possibly making use of a special prosecutor, informs the Ministry of Health of 'clinical investigation, which will test".
The clinical investigation is funded and promoted by the Sponsor (individual, company, institution or organization), which is responsible for initiating and managing the same.
mportant responsibility of the Sponsor is also that of the recording and communication to the competent authorities of serious adverse events, which may have occurred during the trial.
In the context of clinical investigations with medical devices that require authorization from the Ministry of Health, the sponsor is identified with the manufacturer of the medical device.

The four main principles of this "new approach"

The four main principles of this "new approach" provide that:
- The harmonization ensured by the Community legislation is limited to the basic requirements for safety that products must meet in order to be marketed in the Community;
- The development of specific manufacturing techniques already entrusted to the competent bodies in the field of "normalization" industries (in particular, in Europe, the European Committee for Standardization - CEN and the European Committee for Standardization CENELEC);
- The technical specifications determined by these organs do not take mandatory value, retaining the character of voluntary standards;
- Administrations in the Member States are obliged to recognize that products manufactured in accordance with the "harmonized standards" a presumption of conformity with basic requirements of the directives is, and the manufacturer is free to not comply with these regulations, assuming, however, the ' burden - in this case - to demonstrate compliance of its products with the essential requirements.

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Directive

Directive 90/385 / EEC (implemented in Italy with Legislative Decree no. 507/92) concerning active implantable medical devices, Directive 93/42 / EEC (enforced by Legislative Decree no. 46/97) on medical devices, therefore, provide specific and detailed the essential requirements of safety and efficacy to be met by medical devices; in order to prove compliance with the requirements of its medical devices essentialist them provided, a manufacturer may apply "rules" existing techniques.
It 'important to reiterate that the application of technical standards by manufacturers is voluntary,

TRACEABILITY

DOCUMENTED PROCEDURES TO GUARANTEE IT

EXTENT AND RECORDS

PRODUCTS COMPONENTS

MATARIALS

ENVIRONMENTAL CONDITIONS

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Manufacturer information

Any medical device must be accompanied by the requisite information to facilitate the correct identification of the device and its manufacturer, its intended use and the procedure for safe use:

- Label
- Instruction for use (maintenance)

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LABEL
(PRINTED OR GRAFICALLY)

POSTED ON THE MEDICAL DEVICE OR ON ONE OF ITS WRAPPING

ACCOMPANIES THE MEDICAL DEVICE

TECHNICALLY IDENTIFIES AND DESCRIBES THE DEVICE

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Medical Devices for diagnostic use

Directive 98/79 / EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, they have been introduced at European level the requirements to uniform level of safety, quality and performance of in vitro diagnostic medical devices (Directive 98/79 / EC1)

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What is this?

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 from the human body, including blood and tissues donated, solely or principally for the purpose of providing information concerning a physiological state co or pathological, or a congenital abnormality, or information to help determine the safety and compatibility with potential recipients, or to monitor therapeutic measures. "

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Requirements

Calibrators and control materials intended to verify the performance of an in vitro diagnostic device that have a value assigned and are traceable to a certified reference material, are in vitro diagnostic medical devices. Control materials without assigned values, are employed for reproducible measurements in a lab, then used as controls for precision in programs External Evaluation of Quality and distributed exclusively for checks of the accuracy of measurement does not fall within the Directive.

Equipment such as scales, centrifuges, test tubes, pipettes, solutions and microscope slides, should not be CE marked because their use is outside the scope of the directive.

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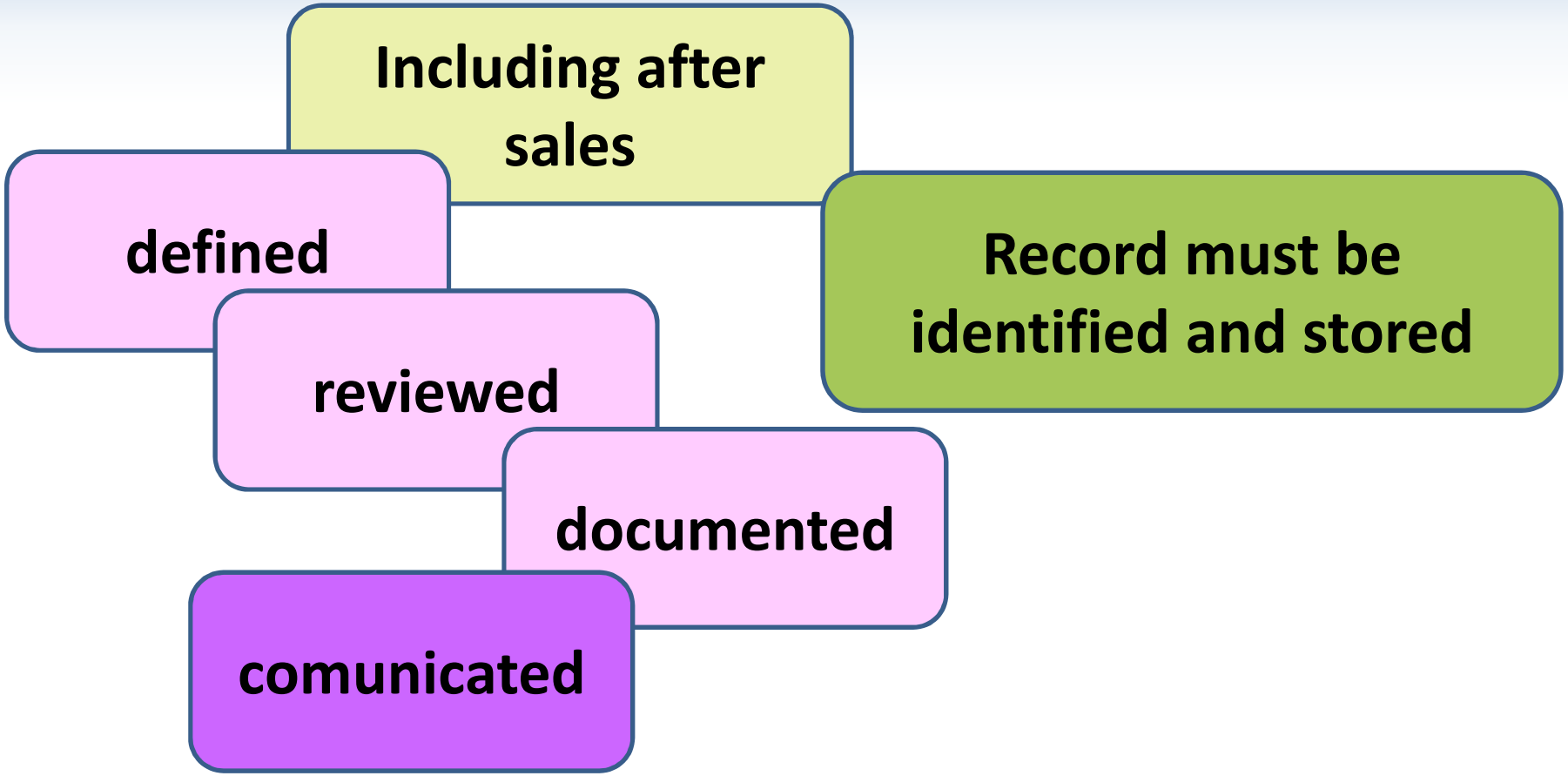
Device requirements



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Other requirements

The general requirements are addressed to the intrinsic safety of in vitro diagnostic medical device and related to:

- Health and safety of patients and users
- Risk analysis
- Minimizing the risk associated with the use
- Performance evaluation in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility

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Preservation of product

Documented procedures to:

- Preserve the conformity of product during manufacturing and until to delivery to his destination;

- Guarantee product contol with limited shelf life and/or special preservation;

THE DEVICE MUST BE IDENTIFIED DURING EVERY PHASE OF REALIZATION.

THE IDENTIFICATION MODALITY MUST BE DOCUMENTED.

THE DELIVERED DEVICES MUST BE IDENTIFIED AND SEGREGATED THAN THE ACCORDANT ONES

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Feature of 13485

The system's requirements to the management of the specified quality are complementary to the technical requirement to devices.

This regulation is not intended to facilitate the harmonization of regulatory requirements to the management system globally to the quality.

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When a regulation is harmonized?

Although regulations are considered harmonized after the publication of references on the Official Journal, is just the publication that confers it the compliance's presumption of directive's essential requirements.

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Purchasing

The mode of supply management should be documentated.
Suppliers should be assessed and records must be kept of the assessments should be maintained.
Documents and records must be retained as a contribution to supply traceability.
The supplied devices must be verified to ensure their adequacy in ralation to specifed requirements.
Second part audits at the supplier could be an appropriate verification element.
The records of all activities must be preserved

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Control of processess in outsourcing

1) **It must be reserve particular attention to the outsourced process and the extension of the control is influenced from the complexity of the outsourced process.**

2) **The control's extension must allow for every phase of the operative process, not only for the final product.**

3) **Over the statistical control would be better check whether before the commitment of the activities or during the contract.**

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PARTICULAR REQUIREMENTS FOR STERILIZED MEDICAL DEVICES

ALL ACTIVITIES CONNECTED WITH THE STERILIZATION MUST BE RETAINED FOR EVERY SHARE

THE STARILIZATION PROCESS MUST BE CONFIRMED BEFORE THE FIRST USE AND RECORDINGS MUST BE PRESERVED.

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Measuring devices

a) Calibrated or verified at specified intervals;

b) Be adjusted or re-adjusted as necessary;

c) Identified to enable calibration status

d) Safeguarded from adjustments that would invalidated mesasures

e) Proteced from damaging anddeterioration during handling, maintenance and storage.