Title: Combination of CE-marked and non-CE-marked medical devices and non-medical devices into systems and procedure packs

NB-MED/2.9: Systems and procedure packs per the Medical Devices Directive 93/42/EEC: application of Art 12 or Art 11

1. Purpose

The purpose of this recommendation is to provide guidance to the Notified Body and the manufacturer on the regulatory requirements which apply to the placing on the market and putting into service of various combinations of CE-marked medical devices, non CE-marked medical devices and non medical devices. This includes guidance on the application of Article 11 or Article 12 of Directive 93/42/EEC.

2. Scope

This document applies to all products described as systems or procedure packs under the Medical Devices Directive 93/42/EEC. See Section 6 for suggested definitions of these terms.

There are no explicit provisions for systems and procedure packs under the Active Implantable and In Vitro Diagnostic medical devices directives which are therefore outside the scope of this document.

This document also contains guidance on the inclusion of products which are not medical devices into systems and procedure packs.

3. Background:

Systems and procedure packs are typically combinations of medical devices and accessories packaged and sold together and may also include non-medical devices.
Although the two terms “systems” and “procedure packs” can apply to combinations having different characteristics (see Definitions below), there is no regulatory difference to the way they are treated under Directive 93/42/EEC.

This document is developed to facilitate a consistent approach to the application of article 11 and 12 for systems and procedure packs.

4. Legislation:

- Directive 98/79/EC on In Vitro Diagnostic medical devices (IVD)
- Directive 76/768/EEC on Cosmetics
- Directive 88/378/EEC on Toys
- General Product Safety Directive 2001/95/EC on Commodities
- Detergents Regulation No. 648/2004
- Any other legislation that may apply to non-medical devices

*Put the proper title and reference to the directives*

5. Other documents used as input:

- MHRA GUIDANCE NOTE 20 Borderlines with Medical Devices - August 2009
- Irish Medicines Board Guide for manufacturers of systems and procedure packs regarding legislative requirements, guidance note 25 – version 0, December 2006
- Meddev 2.4/1, classification of medical devices

6. Definitions:
Reference is made to the definitions in the Medical Devices Directive 93/42/EEC, see Annex I. However, because Article 12 of the Medical Devices Directive 93/42/EEC contains no explicit definition of systems and procedure packs, the following definitions are applied in this document. It should also be noted that, despite these suggested definitions, the terms are often used interchangeably in different medical devices sectors.

**Procedure pack**: a grouping of medical devices that are packaged together and placed on the market with the purpose of all being used in one medical treatment or a surgical procedure. Procedure packs are typically intended for single use. The components of the procedure pack are normally used in combination or at the same time. The manufacturer of a procedure pack may manufacture all of the components or source them from different manufacturers.

Some examples of procedure packs include:
- Surgical packs for specific procedures
- Theatre dressing packs
- Orthodontic procedure packs

**System**: a grouping of medical devices that are packaged together and placed on the market with the purpose of being used for a medical treatment, diagnosis or monitoring, or a surgical procedure, whereby the medical professional selects from the system the medical devices for the medical procedure.

This definition covers the combination of 2 or more medical devices (either packaged together or not) which are intended to be inter-connected and which may include active and non-active medical devices, that is placed on the market by a natural or legal person.

Some examples of systems include:
- Joint replacement system
- Orthopaedic drill system
- Prosthetic system
- Orthotic system
- Ventilation system

Examples of systems that are combinations of active medical devices include:
- Cath lab for cardio-vascular interventions, composed of an X-ray machine, ECG monitor and Contrast injector
- X-ray system for neurological interventions, composed of an X-ray machine, Stereotactic Head frame and 3D Image Processing Software

7. Guidance
7.1 General

A system or a procedure pack can either:
- contain medical devices that are all individually CE marked by the original manufacturer(s)

or
- if one or more of the included medical devices does not bear the CE marking for the use for which it is included then the system or procedure pack must bear a CE marking as a combined product

These two scenarios are further explained below:

7.1.1 Article 12: Systems and Procedure Packs including or containing Medical Devices that are all individually CE Marked by the original manufacturer(s)

Such systems and procedure packs must meet 2 conditions for Article 12 to apply:

1. Every individual medical device placed on the market as part of the system or procedure pack bears the CE marking in a visible, legible and indelible form:
   (a) on the medical device or its sterile pack, where practicable and appropriate;
   (b) on the instructions for use of each medical device; and
   (c) on any sales packaging
   This includes the cases where the valid CE mark of the medical device is removed with the packaging when placing in the procedure pack

2. The individual medical devices which are part of the system or procedure pack are not put to a different use to that intended by the original manufacturer(s) of the medical device(s).

In such cases, the outer pack label shall not bear an additional CE marking but it shall be accompanied by the information needed to use the medical devices safely and to identify the medical devices, and the manufacturer(s), taking account of the training and knowledge of the potential users (see section 7.2.3 for more detail).

Systems may contain active devices which may not necessarily be packaged together for sale but, instead, may be assembled together on site.

In such cases, the following additional information may need to be provided on the label(s):
- An expiry date based on the shortest dated component or on the sterilisation shelf life (where applicable), whichever is the shortest, unless no shelf life is defined for any of the devices in the system
- A specific lot or serial number for the system to allow for traceability of the medical devices in the system.
The manufacturer should provide instructions for use for the individual medical devices in accordance with the original manufacturer's labelling, including any warnings and precautions.

Even if the system or procedure pack can be treated under Article 12 as above, the manufacturer can nevertheless choose to apply the requirements of Article 11 and thus take over the full legal responsibility for all the medical devices in the procedure pack under Article 11 - see below.

**7.1.2 Article 11: Systems or Procedure Packs containing Medical Devices that do not all individually bear the CE Marking for the purpose intended by the system or procedure pack manufacturer or assembler**

This route is used where
   a) The combination of devices does not meet the conditions described above
   b) The manufacturer chooses not to use the derogation set out in Article 12

In this case, the system or procedure pack is treated as a medical device in its own right, and the conformity assessment route undertaken is determined by the medical device component with the highest medical device classification or by the intended purpose of the system or procedure pack.

The outer pack must bear the CE marking for the pack including the Notified Body number where applicable and the pack must be labelled in accordance with the labelling requirements of the medical devices directive, ie the pack should be accompanied by the information to use it safely and as intended.

If any of the included devices can be reprocessed then reprocessing instructions should be provided in accordance with EN ISO 17664.

If any of the included devices requires maintenance or calibration, appropriate instructions should be provided.

As the physical removal a CE mark may introduce unjustifiable product risks, the system or procedure pack can contain medical devices that still bear the original manufacturer's CE mark. The justification for presence of CE marking on individual medical devices or their primary packaging should be documented.

**7.2 Obligations of procedure pack manufacturers:**

**7.2.1 Declaration for systems and procedure packs:**
7.2.1.1 Declaration per article 12

The manufacturer placing the system or procedure pack on the market should draw up a declaration that:

(a) he has verified the mutual compatibility of the medical devices in accordance with the manufacturers' instructions and he has carried out his operations in accordance with these instructions;
(b) he has packaged the procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
(c) his operations are subjected to appropriate methods of internal control and inspection.

By analogy with the administrative provisions of the Conformity Assessment Annexes, the above declaration should be kept available for inspection by the Competent Authorities for a period of five years or 15 years when the procedure pack contains implantable medical devices.

7.2.1.2 Declaration of conformity via Article 11

The manufacturer placing the system or procedure pack on the market under Article 11 must draw up an EC declaration of conformity for the system or procedure pack as a medical device in its own right.

7.2.2 Technical Documentation:

7.2.1.1 General

In order to fulfil the requirements of both conformity assessment under Article 11 and of mutual compatibility, internal control etc under Article 12, the system or procedure pack manufacturer needs to obtain information on the included medical devices including but not limited to shelf life limitations, storage and transport conditions, other relevant EU Regulations or Directives that apply to the medical device, materials of construction of the medical device, the need to retain the primary packaging.

In particular, the original manufacturer name and certification status need to be known in order to determine the application of Article 11 or 12 for the system or procedure pack.

When the medical device is CE marked, the following documents can provide the some of the required information

- the CE certificate(s)
- the Declaration of Conformity,
The system or procedure pack manufacturer also needs to know the name of the Notified Body if applicable and the classification of the medical device which is relevant to the classification of the system or procedure pack under. However, this classification may change depending on the use of the device in system or procedure pack.

The above information may be obtained in the form of a medical device questionnaire. An example of a typical medical device questionnaire is presented in Annex II.

When the included medical device is already CE marked, the system or procedure pack manufacturer can rely on the original manufacturer for information to ensure that the medical device complies with the requirements of the Medical Devices Directive. However, in order to comply with the regulatory requirements, an exchange of information between both parties is needed.

The system or procedure pack manufacturer and the original manufacturer(s) should also have an agreement covering elements such as but not limited to:
- location and availability of Technical Documentation
- Change control regarding CE marking of the medical device, certification status of the original manufacturer, changes that affect the information as listed in section 7.2.2.1, Notified Body
- Traceability of the medical device in the procedure pack
- Responsibilities and actions in case of non-conforming products, vigilance and Field Safety Corrective Actions.
- Audit by a Competent Authority or a Notified Body

The manufacturer should ensure that the system or procedure pack includes appropriate instructions for use for all the medical devices used, including applicable warnings and precautions. The warnings and precautions may also assist the system or procedure pack manufacturer in assessing the mutual compatibility of the medical devices in the procedure pack.

Additional information to be provided on the label for all systems and procedure packs:
- An expiry date based on the shortest dated component or on the sterilisation shelf life (where applicable), whichever is the shortest.
- A specific lot number for the procedure pack to allow for traceability of the medical devices in the pack.

The system or procedure pack manufacturer needs to know what sterilisation parameters are normally used for the medical device in order to evaluate the compatibility with the sterilisation process with the included products.

7.2.1.2 Article 11
The manufacturer must prepare the appropriate technical documentation for the system or procedure pack as a medical device in its own right as specified in the Conformity Assessment Annexes of the Medical Devices Directive. Further guidance is given in NBMED 2.5.1 Rec 5 Technical Documentation.

The labelling requirements are as listed in the Medical Devices Directive Annex I section 13.

The label of the system or procedure pack will bear only one CE mark and the Notified Body number if applicable. (Unless there is a PPE usage in which case the Commission Interpretative Document INTERPRETATION OF THE RELATION BETWEEN THE REVISED DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES AND DIRECTIVE 89/686/EEC ON PERSONAL PROTECTIVE EQUIPMENT refers).

In order to identify the medical devices, the system or procedure pack manufacturer should list the medical devices, and their CE mark (how can you list a CE-mark?) and Notified Body, number where applicable, on the outer label.

The system or procedure pack manufacturer should provide instructions for use in accordance with the requirements of the Medical Devices Directive Annex I section 13.6.

7.2.1.3 Article 12

Under Article 12, the original manufacturer retains the responsibility for the medical device included in the system or procedure pack. (Is this completely true?)

The manufacturer shall provide instructions for use for the individual medical devices in accordance with the original manufacturer’s labelling, including any warnings and precautions.

7.2.4 Sterilisation

Article 11: there is no difference between sterilisation of a system or procedure pack and sterilisation of a medical device

Article 12: when a system or procedure pack requires sterilisation, the manufacturer must follow either Annex II or V of the Medical Devices Directive, limited to NB assessment of the packaging and sterilisation activities performed by the manufacturer. The system or procedure pack manufacturer should sterilise the
system or procedure pack taking into account original manufacturers’ instructions for the included devices.

Article 12 para 3: the manufacturer must shall draw up a declaration stating that the sterilization has been carried out in accordance with the original manufacturer’s instructions. These instructions refer to the sterilisation method and critical parameters that may affect the medical device functionality and performance.

**7.2.5 Traceability & vigilance**

Article 11: there is no difference between the vigilance requirements for a system or a procedure pack and for a medical device. However, it is recommended that there is an exchange of information with the manufacturers of the included medical devices in order that they can take any appropriate action based on experience of their device in the system or procedure pack.

Article 12: the manufacturer of the system or procedure pack should have an agreement with the original manufacturer(s) of the included medical devices outlining the responsibilities and actions in case of non-conforming products, vigilance and Field Safety Corrective Actions.

**7.3 Obligations for Notified Bodies**

**7.3.1 Article 12, no sterilisation:**

There is no Notified Body intervention for these.

**7.3.2 Article 12, including sterilisation:**

The review by the Notified Body of the application of Annex II or V is limited to the packaging and sterilisation activities performed by the manufacturer.

The certification scope is: ‘securing and maintaining sterile conditions per Article 12’ –see NBOG 2010-3

**7.3.3 Article 11:**

There is no change from the conformity assessment of single medical devices.
Combination of systems and procedure packs with other products (not regulated by 93/42/EEC)

Background:

The Directive explicitly covers the case of systems or procedure packs containing medical devices. In certain cases the system or procedure pack manufacturer may wish to include products which are not medical devices for the convenience of the customer.

The following guidance is intended to cover this case and is based on the premise that 93/42/EEC requirements apply to the medical devices exclusively. The regulatory requirements that apply to any included products which are not medical devices are defined by the regulation applicable to the individual product to be included.

The manufacturer of the system or procedure pack must also ensure that the requirements of any other applicable regimes are met.

7.2 Elements to be considered for the combination:

7.2.1 Mutual Compatibility

There should be no adverse interaction between the other products and the medical devices within the system or procedure pack when the combination is used as intended.

7.2.2 Intended Use

The combination of the other products within the system or procedure pack must not change the intended use of the medical devices or of the other products.

7.2.3 Classification

The combination of the procedure pack under ART 11 with other products does not affect the classification of the procedure pack. Inclusion of a drug?

7.2.4 Labelling

The labelling should make it clear that the system or procedure pack includes both medical devices and other products.

The labelling of the combination should comply with the requirements of the Medical Devices Directive and the other applicable directives as they apply to the other products.

The included medical devices and the other products should be clearly differentiated in the labelling.
Inclusion of non-medical devices may require multiple CE marks in the labelling, for example see The CE marks have to be appropriately assigned to the products in the labelling. For example, see the Commission Interpretative document "INTERPRETATION OF THE RELATION BETWEEN THE REVISED DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES AND DIRECTIVE 89/686/EEC ON PERSONAL PROTECTIVE EQUIPMENT". Application of this document necessitates placing the CE mark NB number which carried out any conformity assessment under 89/686/EEC on the labelling.

Combination of a procedure pack with other products that do not have a CE mark should be clearly differentiated in the labelling between the CE marked and the non-CE marked products.

7.3 Elements to be considered for the procedure pack:

The manufacturer must take into account any additional impacts of the other products on the procedure pack manufacturing process, for example increased levels of bioburden may require changes to the sterilization process.

7.4 Elements to be considered for the other products:

7.4.1 Regulatory Compliance:

The manufacturer has to identify the regulatory regime that is applicable to the other products and ensure that the other products placed on the market in the combination still comply with these requirements. The manufacturer must ensure that procedures are in place to comply with the post marketing and incident reporting requirements of the applicable regulatory regime. For example, local approvals are required for placing biocidal products on the market in individual EU Member States; traceability to the patient is required for Active Implantable Medical Devices.

7.4.2 Product compliance:

The manufacturer should verify that the manufacturing process of the procedure pack, including sterilization, does not adversely affect the other products.

7.4.3 Sterilisation:

In the situation that a manufacturer sterilizes the other products together with the procedure pack, and where no specific standards exist for the sterilization of the other products, the manufacturer is recommended to use the standards applicable to medical devices. For example, EN ISO 11135 series can be used for validation of sterilization of the other products.
For example, the applicable parts of EN ISO 10993 can be used for assessment of the biocompatibility of the other product.

7.4.4 Risk Management:

The manufacturer must be aware of the risks associated with the inclusion of other products in the procedure pack to the intended user or patient and undertake appropriate risk mitigation measures. For example, when the procedure pack consists of only latex-free devices and the other product contains latex, as a minimum, this should be identified on the labelling.

7.5 Special considerations for the combination of systems and procedure packs with medicinal products:

7.5.1 Marketing Authorisation (MA) holder:

The manufacturer needs to identify the MA holder of the medicinal product. The following elements need to be considered with the MA holder:
- type of registration procedure (Centralized Procedure, National Procedure, Mutual Recognition procedure, Decentralized Procedure) because this will determine in which countries the medicinal product can be distributed
- requirements regarding the labelling, especially when a part of the labelling is removed and has to be reproduced on the labelling of the combination
- possible manipulations of the medicinal product which may compromise the registration status of the medicinal product (e.g. unpacking, (re)sterilization, bundling, breaking into smaller units) by the manufacturer when it is being placed in the combination,
- When the above listed issues are agreed upon with the MA holder, the manufacturer has to take the following steps:

7.5.1.1 Manufacturing licence:

The manufacturer will have to apply to the local medicinal product Competent Authority for a manufacturing licence for putting the finished medicinal product in the combination. The scope of the manufacturing licence will differ when he breaks down the MA pack size of the medicinal product or re-sterilizes it with the procedure pack. The manufacturer has to comply with the EU Good Manufacturing Practices (GMP).

7.5.1.2 Distribution licence (or wholesale dealer’s licence):

The manufacturer will need a distribution licence from the Competent Authority in the country where the distribution warehouse is located. This requires compliance with the Good Distribution Practices (GDP) Regulation. If the manufacturer only
distributes through an independent agent(s), only the agent(s) need the distribution licence.

7.5.1.3 Pharmacovigilance:
Pharmacovigilance for the medicinal product is the responsibility of the MA holder. The MA holder and the manufacturer of the combination will need to ensure that all complaints on the medicinal product in the combination are captured and forwarded to the MA holder.

7.6 Obligations for Notified Bodies

7.6.1 General:
The Notified Body per Directive 93/42/EEC is not involved in the placing on the market of the ‘other’ product(s) except:
- as they impact the use of the medical devices within a procedure pack which they are conformity assessing under Article 11
- as they impact the sterilisation of the pack under Article 12

7.6.2 Systems and procedure packs per Article 12, no sterilisation:
Under the Medical Devices Directive, there is no requirement for any Notified Body involvement related to the placing on the market of systems and procedure packs per Article 12 that are not sterilised by the procedure pack manufacturer.

7.6.3 Systems and procedure packs per Article 12, including sterilisation:
For the procedure pack, the Notified Body obligations are explained in NB-MED 2/9 Rec 1. The Notified Body will have to verify that the inclusion of the ‘other’ product(s) in the combination does not adversely affect the sterilisation and packaging validation of the procedure pack.

7.6.4 Systems and procedure packs per Article 11:
The procedure pack manufacturer will choose one of the conformity assessment routes defined in Article 11, in line with the classification of the procedure pack. The Notified Body will perform the assessment per the applicable Annex of the Medical Devices Directive and will issue the appropriate certificate when the relevant requirements are met. The Notified Body will verify that the manufacturer has taken into account the elements addressed in this guidance document under 7.1, 7.2 and 7.3.
Annex I: Definitions

Per Medical Devices Directive 93/42/EEC:

‘medical device’ means 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 medical purposes 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;

‘manufacturer’ means the 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.

The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made medical devices and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient;

‘intended purpose’ means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

‘placing on the market’ means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a
view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

‘putting into service’ means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose;
Annex II: Example of medical device questionnaire

Medical Device Questionnaire

1. Medical device general information:

   (a) Medical device name:
   (b) Reference number (attach a list for multiple numbers, if necessary):
   (c) Description (e.g. dimensions, size, list of accessories etc., where applicable):
   (d) Intended use of the medical device:
   (e) Does the medical device have a limited shelf life? [Yes/No]
      (Delete as appropriate)
   (f) If yes, what is the shelf life of the sterile device?
      What is the shelf life of the non-sterile device?
   (g) Are there any specific requirements for storage and/or transport of the medical device? [Yes/No]
   (h) If yes, please give details:
   (i) Where supplied, what is the format of the instructions for use (insert, labelling, carton etc.)
   (j) Where supplied, please provide a copy of the instructions for use in a suitable format
   (k) Into what languages are the instructions for use currently translated?
   (l) When no instructions for use are available and the device is for single use, are there any risks related to the reuse of the device? (please specify)

2. Manufacturer information:

   (a) Complete name and address of the Manufacturer (as defined in the Council Directive 93/42/EEC):
   (b) Complete name and address of the Authorized Representative, where applicable:
   (c) Please provide a copy of the Manufacturer’s QMS certificates (ISO 13485, ISO 9001 etc.) if applicable
   (d) Please provide the name and address of the QA/RA contact person of the manufacturer:
   (e) Please provide the name and address of the Medical Device Vigilance contact of the manufacturer (not applicable if the medical device is not CE marked) if different from 2(a) or 2(b)
3. Medical Device CE related information:

(a) Is this a medical device per Council Directive 93/42/EEC? Yes/No
    If No, go to section 4.
(b) Is the medical device CE marked? Yes/No
    If No, go to section 4.
(c) What is the device classification per Annex IX of 93/42/EEC? 
(d) Which classification rule has been applied per Annex IX of 93/42/EEC? 
(e) Notified Body name and number: 
(f) Please provide a copy of the CE certificate and/or Declaration of Conformity
(g) Please provide a copy of the Design Examination certificate for Class III devices
(h) Please provide a list of the applicable product specific (vertical) standards (ISO, EN, others) that have been used to demonstrate compliance with Essential Requirements in Annex I of 93/42/EEC.
(i) Please provide a list of any other relevant EU Regulations/Directives to which this medical device complies:

4. Medical device material related information:

(a) Your medical device will be placed in a Procedure Pack; does your medical device need to remain in its primary packaging? Yes/No/NA/
    (b) If yes, please give details:
    (c) Please list the materials of construction, including the primary packaging:
    (d) Does the medical device or it’s primary packaging contain
        o Natural Rubber Latex Yes/No
        o Chlorinated Polymer, e.g. PVC Yes/No
        o Phthalates, e.g. DEHP Yes/No
        o Materials of human or animal origin Yes/No
    (e) If the answer is Yes to any of the materials listed above, please give details:
5. Sterilization information:

(a) What is the mode of delivery of the medical device? (sterile/non sterile, individual packaging/bulk):

(b) Where applicable, are non-sterile bulk medical devices delivered in cardboard shipper cartons with double liner bags to protect the medical devices from foreign particles? Yes/No

(c) If the medical device is provided sterile, what is the method of sterilization? (EtO, Irradiation, Moist Heath, Other – please specify):

(d) Can the medical device be (re)sterilized by means of EtO, Irradiation, Moist Heath, Other – please specify:
   Does the (re)sterilization impact the shelf life or performance of the device? Yes/No/Unknown
   If yes, please specify.

(e) Where applicable, please provide the critical re-sterilization parameters (e.g. max temp and pressure for EtO):

(f) In case the medical device is sterilized by EtO, how many resterilization cycles have you validated for your medical device?

(g) What is the bioburden (average/limit) of the medical device, expressed in CFU (Colony Forming Units)?

(h) Where applicable, are the medical devices which are delivered bulk non-sterile manufactured in exactly the same process and released based on the same specifications as the sterile CE marked medical devices apart from the final packaging and sterilization? Yes/No

(i) Where applicable, are the medical devices which are delivered non-sterile in individual packaging manufactured in exactly the same process and released based on the same specifications as the sterile CE marked medical devices apart from the sterilization? Yes/No
Medical device Questionnaire Notes

1. Medical device general information:

This section provides the procedure pack manufacturer with general information about the medical device.

Question (d): this is asked to ensure that the medical device when placed in the procedure pack has the same intended use as the standalone medical device. If the intended use is different the procedure pack manufacturer will have to follow Article 11 instead of Article 12.

Question (f): this aims to clarify whether the indicated shelf life has been assigned based on maintenance of sterility by the primary packaging or on deterioration of medical device characteristics.

Questions (i), (j) and (k): these are included as the procedure pack manufacturer needs to ensure that appropriate instructions for use are provided for the medical device in the procedure pack.

Question (l): this question is included because single use devices without instructions for use may have risks related to reuse. The manufacturer of a procedure pack under ART 11 has to be aware of these risks, to include them in the general risk assessment, and to meet the Essential Requirement 13.6 (h).

2. Manufacturer information:

When a procedure pack manufacturer places a medical device into a procedure pack it is evident that the original manufacturer name and certification status need to be known. Under Article 12 the original manufacturer retains responsibility for the medical device included in the procedure pack.

3. Medical Device CE related information:

Question (a) and (b): It is important for the procedure pack manufacturer to know whether the medical device is CE marked in order to decide whether the medical device can be included in an Article 12 or Article 11 procedure pack.

Question (c): The device classification can be relevant to the class of the procedure pack under Article 11.

Question (d): The device classification rule provides understanding to the procedure pack manufacturer of the classification decision.
Question (e): The Notified Body Name and Number give a unique identification of the Notified Body. The address can be easily obtained based on this information from the NANDO website of the EU Commission.

Question (h): this relates to the fact that for systems and procedure packs under Article 11, the procedure pack manufacturer needs to verify that after sterilization the medical device still has the same product performance characteristics. This can be done by using the same standards as the original manufacturer.

Question (i): This question relates to the fact that certain devices will also be subject to other regulations such as WEEE, PPE, … . The Procedure Pack Manufacturer must take the requirements of these regulations into account where applicable.

4. Medical device material related information:

Question (a): The intention of the procedure pack is to unpack the medical device as much as possible. Sometimes the primary packaging is needed to ensure that the medical device performs as per intended use.

Question (c), (d) and (e): these relate to the material characteristics of the medical device. This information is required for the procedure pack manufacturer Risk Assessment and to meet the Essential Requirement 7.5.

5. Sterilization information:

Question (c): this relates to the impact that the original sterilization can have on medical device characteristics and subsequent (re)sterilizations.

Question (e): this information is essential as per Article 12 the medical device has to be sterilized according to the original manufacturer’s instructions. For Article 11, the procedure pack manufacturer needs to know what sterilization parameters are normally used for the medical device, to evaluate the compatibility of his own sterilization process compared with these parameters.

Question (g): Under Article 11 the procedure pack manufacturer needs to know the bio-burden of the medical device to evaluate whether the bio-burden remains within the limits defined by the sterilization process. It is the procedure pack manufacturers’ responsibility to evaluate the impact of his process on the initial bio-burden to ensure that the final bio-burden meets the parameters of his sterilization validation.

Question (h) and (i): The procedure pack manufacturer wants to rely on the original manufacturers’ Technical Documentation for those elements that are not related to the sterilization of the device to demonstrate compliance with the Medical Devices Directive requirements.
6. Reprocessing:

Procedure packs are typically single use, so reprocessing instructions would not apply. For systems that contain devices that can or have to be reprocessed, the reprocessing instructions must be included in the labeling of the system.

7. Maintenance/calibration:

Systems can contain devices that require maintenance or calibration. The labeling of the system has to include the appropriate instructions.
Rationale and history sheet:

This document was generating by combining the following drafts:

- NB-MED/2.9 Rec 1: Procedure packs per the Medical Devices Directive 93/42/EEC – August 2008
- NB-MED/2.9 Rec 2: Combination of procedure packs with other products (not regulated by 93/42/EEC) – January 2009
- NB-MED/2.9 Rec 3: Additional guidance for Systems – January 2010

The rationale for combining the documents is that:

1. There is not regulatory difference between the treatment of “Procedure Packs” as described in Rec 1 above and “Systems” as described in Rec 3.
2. Many “systems” and “procedure packs” also contain products which are not regulated by 93/42/EEC and so it makes sense to cover this situation in a single document
3. The combined length of the 3 documents above (not including rationales) is about 33 pages, and the combined document is significantly shorter because of the removal of the repeated elements.