Joint Action Project "COEN JA2014"
Instructions For Use for reusable and resterilisable Medical Devices

COEN

What is a Medical Device?

Medical devices (MD) are regulated under the European Directive 93/42/EC also called the "medical device directive" (MDD).

MD are 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.

MD are classified into 4 risk levels: class I, IIa, IIb, III. Class III is the highest risk level.

Some MD can be used more than once. These are called "reusable" MD. These reusable MD can be either easy to use or needing more specific information like the sterilisation process so they can be used safe and effectively again.
Invasive reusable surgical instruments may fall into class I and others may fall into higher classes such as class IIa.

What is COEN?

The Compliance and Enforcement Group referred to as COEN is a European working group. Its main objective is to harmonise the exchange of information between Competent Authorities (CA) responsible for market surveillance (MSA) of MDs and to coordinate their activities in the MD-market. This is especially important because the EU is a single market and once a product has achieved a CE mark, it can be placed freely on the market across the EU. The COEN Group is also to consider how communications and co-operation between Member States can be made more effective and efficient.

What is a Joint Action?

A Joint Action (JA) is an initiative within the second Public Health Programme conducted by national CAs and other public bodies or non-governmental organisations nominated by the European Member States or other participating countries.
JAs are jointly funded by the partners and the European Commission[1].
JAs proposals should provide a genuine European dimension in order to make sense both technically and in terms of policy[2].

Why is there a project COEN JA2014?

Over the recent years, European Member States are reinforcing the marketing surveillance for MD. This reinforcement focuses mainly on a better harmonisation in the market surveillance and an improvement in the coordination of activities. The project COEN JA2014 evaluates the fulfilment of regulatory requirements in the field of reusable/resterilisable medical devices on a European level, thus allowing further developments in the coordination and promoting harmonisation and cooperation. Furthermore, it aims to improve the transparency regarding the actual compliance of MDs to be reusable/resterilisable.

[1] Joint Actions – EU support for key public health initiatives 2008-2011
[2] Funding under the 3rd Health programme 2014-2020

Which member States are involved?
The following member states and EEA members are taking part in the JA: Austria, Belgium, Croatia, Greece, Hungary, Ireland, Italy, Portugal, Slovakia, Spain, Sweden, UK & Norway. Additionally, Germany, Netherlands, Malta, Estonia & Switzerland are assigned as collaborating partners.

Importantly, the outcomes of this JA will be disseminated across all Member States regardless of their participation, which will help to spread a consistent approach and best practice across the entire European regulatory network.

Why is there a focus on the Instructions For Use?
An "Instructions For Use" (IFU) should contain all the necessary information on how to use the MD properly. Inadequate IFUs can result in the device not being re-sterilised properly which can in turn lead to serious hospital-acquired infection at the patient level.
Initial market surveillance activities on a small scale in the field of reusable/re-sterilisable medical devices have shown that the standard of IFUs and the supporting validation processes are open for improvements.

According to Annex I, 13 of the MDD, each device must be accompanied by the information needed to use it safely and properly. Nevertheless there is a generic exception that the IFU is not needed for MD in Class I or IIa if they can be used safely without any such instructions.
However, the reusable MD have often e.g. geometrical or physical properties that may render the reprocessing difficult or questionable, as well these products do require sound and precise processes to be reusable. Therefore the above mentioned exception is not applicable to reusable MDs as stipulated in MDDD Annex I section 13.6 h *"… **if** the device is **reusable** …" the information for use (IFU) **must** provide," … information on the appropriate processes to allow reuse, **including cleaning, disinfection**, packaging and, where appropriate, the **method of sterilisation** of the device to be resterilised …"*.

How will the project COEN JA2014 proceed?
During this project, economic operators will be chosen depending on different criteria's.

A checklist has been created based on the European harmonized standard EN ISO 17664 - *"Sterilisation of medical devices - Information to be provided by the manufacturer for the processing of re-sterilisable medical devices"* a standard which is meant to facilitate manufacturers in their compliance with section 13 of the essential requirements as set in Annex I of the MDD.
This checklist will be sent to the chosen economic operators to verify whether the IFU contains enough information for the re-sterilisation of these MD.

Afterwards, joint inspections will be prepared in a harmonized way and performed to check the validation of the reprocessing procedures.