NB-MED Position on basic elements to be considered in the application of the Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices (eIFU)

Position 1: Symbol for eIFU

Article 6(1) of the Commission Regulation (EU) No 207/2012 requires:

> *'Manufacturers shall clearly indicate that the instructions for use of the device are supplied in electronic form instead of in paper form.*
>
> *That information shall be provided on the packaging for each unit or, where appropriate, on the sales packaging. In the case of fixed installed medical devices, that information shall also be provided on the device itself.'*

In the absence of specific symbols in harmonized standards Notified Bodies should accept that this requirement is fulfilled if the following symbol and an 'eIFU indicator' adjacent to the symbol is used to indicate that the IFU is provided in electronic form. The eIFU indicator may represent the address of the manufacturer's eIFU website which is required by Commission Regulation (EU) No 207/2012 or any other appropriate indication on the use of eIFUs. The 'indicator' may be placed either alongside, beneath, or surrounding the symbol (as shown below).

eIFU indicator

eIFU indicator

In case an eIFU website address is provided as 'eIFU indicator' the amended symbol should be read 'Consult instruction for use on this website'.

Alternatively, manufacturers may use the following eIFU indicator amended symbol, if this is recommended by applicable harmonised standards for the marketed medical device:

eIFU indicator

eIFU indicator

If an eIFU website address is used, the amended symbol should be read: 'Follow instructions for use on this website'.

Position 2: Applying the regulation 207/2012 on electronic instructions for use of medical devices

Implementing the process of providing IFUs in electronic form instead of paper form for the very first time shall be considered as a substantial change to the Quality System requiring a notification to the Notified Body. This notification shall be accompanied all related QM documents.

Whenever a manufacturer initially decides to use eIFUs for a device or a group of devices the manufacturer shall submit upfront a change notification to the Notified Body. The manufacturer shall provide evidence of compliance of the product with the regulation based on the following:

1. Device (or device group) description, including
2. Labelling for the device (or device group)
3. eIFU rationale demonstrating the applicability of the Regulation and
4. Evidence of compliance with all device related requirements, including
5. Risk Assessment