Manufacturers of medical devices bearing a CE marking may, under certain conditions, provide the instructions for use (IFU) required by Annex I (15) to Directive 90/385/EEC[1], Annex I (13) to Directive 93/42/EEC[2] (MDD) or Annex I (23) to Regulation (EU) 2017/745[3] (MDR) in electronic rather than paper form. These conditions are set out for devices under MDD in Regulation (EU) 207/2012[4] and for devices under MDR in Commission Implementing Regulation (EU) 2021/2226[5]. It also sets out certain requirements for those electronic instructions for use (eIFU) that are provided in addition to the full IFU in paper form, which concern the content of the eIFU and the website requirements.

This document is intended to provide guidance on which documents are typically necessary to enable the smooth review of the documents submitted for an eIFU.

1. **Product** requirements
   An eIFU can only be provided for the following medical devices if the medical devices and accessories are intended for exclusive use by professional users and the use by other persons is not reasonably foreseeable:
   - Implantable and active implantable medical devices and their accessories covered by Regulation (EU) 2017/745 or Directive 93/42/EEC
   - Fixed installed medical devices and their accessories covered by Regulation (EU) 2017/745 or Directive 93/42/EEC
   - Medical devices and their accessories covered by Regulation (EU) 2017/745 or Directive 93/42/EEC and fitted with a built-in system visually displaying the instructions for use
   - Additionally, for software covered by Regulation (EU) 2017/745, manufacturers may provide an eIFU, even if it is intended for use by lay persons

2. Requirements for **labelling on the device** or the **enclosed printed instructions for use** (IFU):
   - Information on the device or in the accompanying documentation that an eIFU is available and how this can be obtained for the specific product. For software covered by MDR, an eIFU may be provided by means of the software itself instead of in paper form.
   - Information on foreseeable emergency situations
     (alternatively: risk assessment that no medical emergency situations are expected that would necessitate additional safety information.)

3. Requirements for the **contents of the IFU** (IFU or eIFU):
   - Evidence that the device is intended for the exclusive use of a professional user, e.g. information in IFU (or reference that it is exclusively software)
   - Where a part of the IFU has to be handed over to the patient, that part must be provided in paper form (e.g. special information for implant owner or an implant pass)
   - The content of the eIFU shall be at least identical with the printed version.
     Multimedia content (e.g. video tutorials) may be provided additionally but not instead of a printed version.

4. Requirements for **risk analysis and risk evaluation**:
   - Content shall cover at least the requirements of Regulation (EU) 207/2012, Article 4 (MDD) respectively Commission Implementing Regulation (EU) 2021/2226 (MDR).
   - The aspects referred to in Article 4 of Regulation (EU) 207/2012 (MDD) respectively Commission Implementing Regulation (EU) 2021/2226 (MDR) should be considered entirely as part of the risk man-

[1] Council Directive 90/385/EEC relating to active implantable medical devices
[2] Council Directive 93/42/EEC concerning medical devices
[3] Regulation (EU) 2017/745 on medical devices
[4] Regulation (EU) 207/2012 on electronic instructions for use of medical devices
[5] Commission Implementing Regulation (EU) 2021/2226 as regards electronic instructions for use of medical devices

agement process. The information can either be included in a separate risk evaluation or in the existing risk management file.

5. Requirements for the **website**:
   - Manufacturer's contact information
     e.g. name, address, telephone / email
   - Information how to identify the correct eIFU
     e.g. how/where the unique identification of the product can be found
   - Information on software- or hardware-requirements to view the eIFU
     e.g. what software is required to view the eIFU and where to obtain it
   - Information how and within which timelines a printed version of the IFU can be obtained free of charge; the timeline shall be a maximum of 7 calendar days
   - Information in which European Union languages the information is available
   - Description that the eIFU is available in a commonly used format that can be accessed with freely available software
   - Description how all previous versions of the eIFU are available on the website, including the date of publication. Previous versions shall be kept available for the following time periods: for devices with a defined expiry date, except implantable devices: 10 years after the last device has been placed on the market (MDR) and at least 2 years after the expiry date of the last produced device (MDD/MDR); for devices without a defined expiry date and implantable devices: 15 years after the last product was manufactured (MDD) / 15 years after the last device has been placed on the market (MDR). Evidence could be provided e.g. by screenshots of the draft website

6. **Contractual regulations** with the internet service provider (ISP) or owner of the website:
   - Description of the measures to prevent hardware or software intrusion or tampering
     e.g. description of cyber security measures or respective certification (e.g. ISO/IEC 27001) of the ISP
   - Description of availability of the website (server downtime, display errors)
     e.g. contractual regulation with internet service provider on availability of the website and reaction (times) in case of outage
   - Description of the long-term reachability of the website
     (for devices with a defined expiry date, except implantable devices: 10 years after the last device has been placed on the market (MDR) and at least 2 years after the expiry date of the last produced device (MDD/MDR); for devices without a defined expiry date and implantable devices: 15 years after the last product was manufactured (MDD) / 15 years after the last device has been placed on the market (MDR)) e.g. contractual regulations with the owner of the internet domain covering the required time frame

7. **Additional requirements**:
   - How is the printed version of the IFU provided within max. 7 calendar days?
     e.g. process description
   - Evidence of verification / validation of the eIFU
     e.g. verification / validation report
   - If the eIFU is provided on a storage media it shall also be provided on a website e.g. description in which form / format the eIFU is provided
   - Devices with internal display:
     - Evidence that displaying the eIFU does not impede the safe use of the device
     - Information on how to start the device
     - The eIFU shall also be provided on a website (and information how to access)
   - Description in which member-states the device is marketed and evidence that the eIFU is available in all relevant Union languages (according to risk management)

- Information on compliance with Regulation (EU) 2016/679[6]
  e.g. confirmation that or how the legal requirements are fulfilled

[6] Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data