IFU CHECKLISTS AS PER EU MDR 2017/745

What is an IFU?

Instructions for Use (IFUs) are documents provided by manufacturers to inform users about a device's intended purpose, proper usage, and any necessary precautions. These documents are particularly significant to ensure the safe usage of the device.

IFUs must accompany all devices, including those with minor modifications intended to enhance product quality, even if the original version is still available on the market.

These documents should include a comprehensive description of the device, highlighting any differences from related products, even if those products are manufactured by the same company.

reachus@easyqsolutions.com

The below checklist will help you to ensure compliance with respect to the IFU requirement in line with EU MDR 2017/745 is as follows:

EU MDR Annex	Requirement	Applicable/Not Applicable	Justify if Not Applicable or Provide Traceability of the Requirement
Annex I General safety and performance requirements Chapter III	The name or Trade name of the device.	*Mention Whether it is Applicable or Not Applicable*	*Incase if the section is applicable provide traceability as to where in the IFU (which section) is this mentioned.* *Eg: Please refer to Section X of the IFU (Doc ID)* *If it is not applicable, provide the justification as to why it is not applicable.* *Eg: This section is not applicable as the device is a non sterile device.*
Annex I General safety and performance requirements Chapter III	The manufacturer's name, registered trade name, or trademark, along with the address of its registered business location.		

Annex I General safety and performance requirements Chapter III	An indication if the device contains or incorporates • a medicinal substance, including a human blood or plasma derivative, or • tissues or cells, or their derivatives, of human origin, or • tissues or cells of animal origin, or their derivatives		
Annex I General safety and performance requirements Chapter III	Storage and/or handling instruction.		
Annex I General safety and performance requirements Chapter III	In case of sterile device, an indication of its sterile state and the sterilization method.		
Annex I General safety and performance requirements Chapter III	Indication of single use if the device is intended for single use.		
Annex I General safety and performance requirements Chapter III	For devices made of substances introduced into the body through an orifice or applied to the skin, which are absorbed or dispersed, provide the overall composition and the quantity of the main components responsible for the intended action.		

Annex I General safety and performance requirements Chapter III	Provide a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users.		
Annex I General safety and performance requirements Chapter III	A specification of the clinical benefits to be expected		
Annex I General safety and performance requirements Chapter III	Links to the summary of safety and clinical performance		
Annex I General safety and performance requirements Chapter III	Provide the performance characteristics of the device.		
Annex I General safety and performance requirements Chapter III	Where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories.		
Annex I General safety and performance requirements Chapter III	Any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard.		

Annex I General safety and performance requirements Chapter III	Details of any preparatory treatment or handling of the device before it is ready for use or during its use.		
Annex I General safety and performance requirements Chapter III	Requirements for special facilities, or special training, or particular qualifications of the device user.		
Annex I General safety and performance requirements Chapter III	The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, details of the nature, and frequency, of preventive and regular maintenance, cleaning or disinfection, identification and replacement of any consumable components, informations on calibration, and risk elimination of installation and servicing devices.		
Annex I General safety and performance requirements Chapter III	In case of sterile devices, instructions in the event of the sterile packaging being damaged or unintentionally opened before use.		

Annex I General safety and performance requirements Chapter III	If the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation.		
Annex I General safety and performance requirements Chapter III	For devices used with other devices or general-purpose equipment: • Provide details to identify compatible devices or equipment for safe use. • Include any known restrictions on device and equipment combinations		
Annex I General safety and performance requirements Chapter III	If the device emits radiation for medical purposes, provide details on its type, nature, intensity, and distribution. Also, explain how to protect patients, users, or others from unintended radiation.		
Annex I General safety and performance requirements Chapter III	Provide warnings, precautions, contra- indications, measures to be taken and limitations of use regarding the device.		
Annex I General safety and performance requirements Chapter III	For implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed must be provided.		

Annex I General safety and performance requirements Chapter III	If the device is intended for use by lay persons, mention the circumstances in which the user should consult a healthcare professional.		
Annex I General safety and performance requirements Chapter III	Include the date of issue for the instructions for use, or if revised, provide the date and identifier of the latest revision.		
Annex I General safety and performance requirements Chapter III	For devices with electronic programmable systems or standalone software, specify the minimum hardware, IT network requirements, and security measures to ensure proper use and protection against unauthorized access.		
Annex I General safety and performance requirements Chapter III	Inform users or patients to report any serious incident related to the device to the manufacturer and the competent authority in their country.		
Annex I General safety and performance requirements Chapter III	Information to be supplied to the patient with an implanted device including Implant card.		