IS YOUR INFORMATION FOR USE COMPLIANT WITH THE MD REGULATION?

Quick Scan to find out if your information for use complies with the requirements of the Medical Directive Regulation (EU) 745/2017

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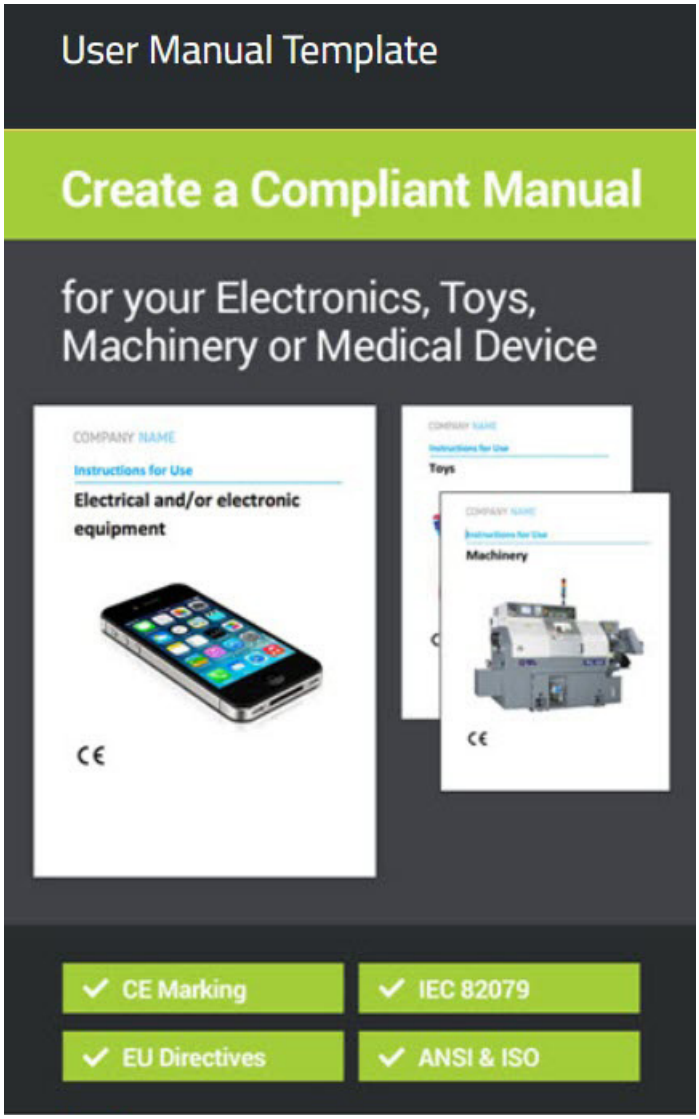

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Checklist for the fulfillment of the requirements on the information for use

Applies to all medical devices

- ☐ The (trade) name of the device.
- ☐ The name and address of the manufacturer.
- ☐ If applicable, an indication that the device contains or incorporates medicinal substances or tissues or cells from human origin or animal origin.
- ☐ Information regarding storage and handling conditions.
- ☐ If the device is supplied in a sterile state, an indication of its sterile state and sterilization method.
- ☐ If the device is intended for single use, an indication of that fact.
- ☐ If device is applicable for in vivo use, information on the in vivo use.
- ☐ The intended purpose of the device as well as the intended users and patient groups.
- ☐ Where applicable, the expected clinical benefits.
- ☐ The performance characteristics of the device.
- ☐ Where applicable, suitable information for the healthcare professional to work with the device.
- ☐ Any residual risks etc. to be conveyed to the patient.
- ☐ Specifications that the user requires to use the device appropriately.
- ☐ Details of any preparatory handling of the device before it is ready for use or during its use, e.g. sterilization or calibration.
- ☐ Any requirements for special training.
- ☐ Information to verify whether the device is properly installed.
- ☐ If the device is supplied in a sterile state, instructions when the packaging is damaged or unintentionally opened.
- ☐ If the device is intended to be sterilized before use, instructions for the sterilization.
- ☐ If the device is reusable, information for allowing reuse.
- ☐ If appropriate, an indication that the device can only be reused if it is reconditioned under the responsibility of the manufacturer to comply with the legislation.
- ☐ If the device is for single use, information on the characteristics and technical factors that could pose a risk if the device were to be re-used.

- ☐ If the device is intended to be used together with other devices, information on the identification of the devices.
- ☐ If applicable, information on the emitted radiation.
- ☐ Information on the limitations of the device.
- ☐ If the device is implantable, information on the materials.
- ☐ Information on the safe disposal of the device.
- ☐ If the device is used by a lay person, the circumstances in which the user should consult a healthcare professional.
- ☐ Issue date and revision date of the IFU.
- ☐ A notice that serious incidents should be reported.

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