

Medical Device IFU

Under the EU MDR (EU 2017/745) and IVDR (EU 2017/746), all medical devices must have an <u>Instructions for Use (IFU)</u> that describes the device's intended purpose, use, proper maintenance, and potential risks. The IFU must also include detailed information on how to safely use the device and how to manage any risks associated with its use as needed in Medical device IFU.

