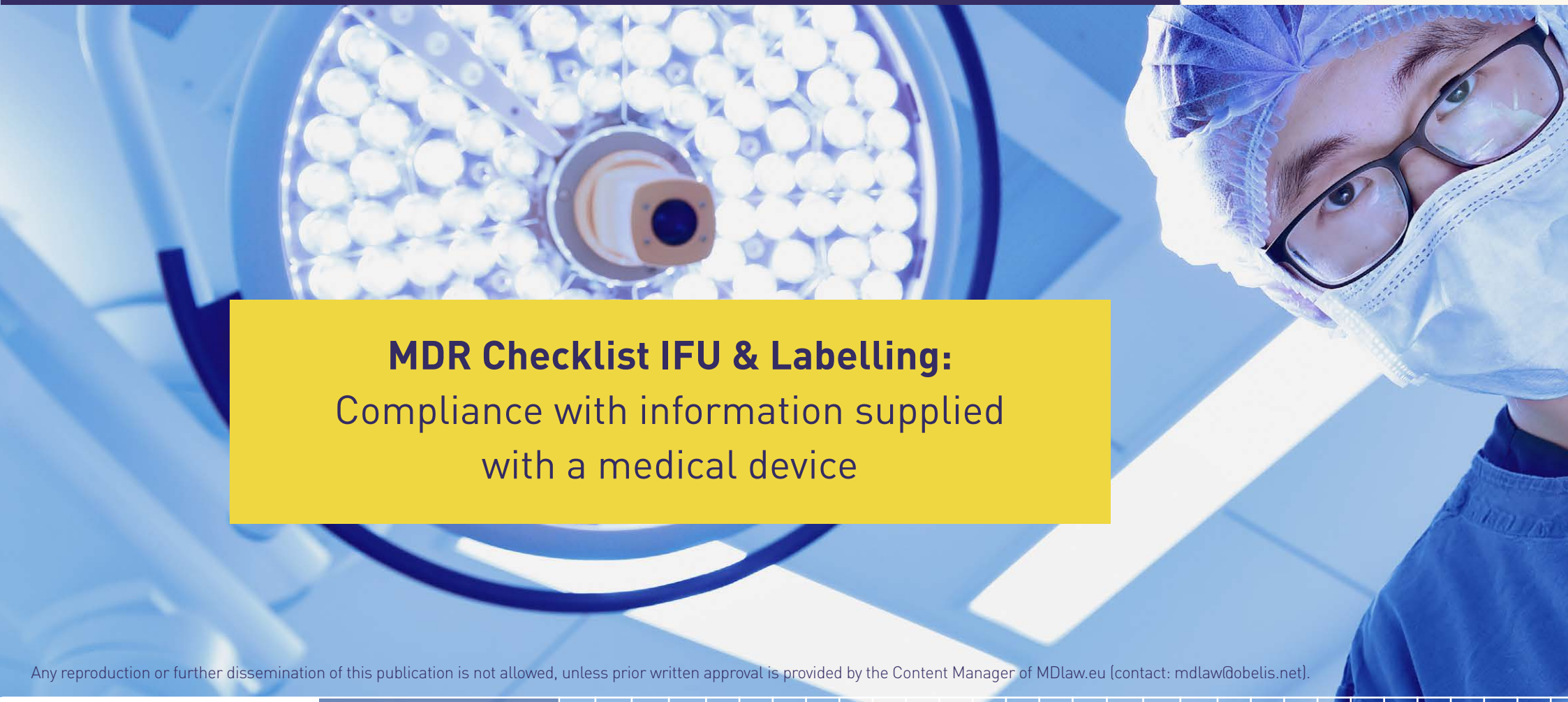
MD Law.eu Information Platform on EU Medical Devices Regulation

MDR
IMPLEMENTATION TOOLS

MARCH 2019



MDR Checklist IFU & Labelling:
Compliance with information supplied with a medical device

POWERED BY OBELIS GROUP

Obelis
CREATES COMPLIANCE FOR SAFER MARKETS

MDR Checklist IFU & Labelling:

Compliance with information supplied with a medical device

Comparison of Requirements of Labels and Instructions for Use Between MDR Regulation 2017/745 and MDD Directive 93/42/EEC			
MDD Directive 93/42/EEC	**MDR Regulation 2017/745**	**Comment**	**Your comments**
General Requirements			
13.1 Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer. This information comprises...	23.1 Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by ...	23.1 of the Regulation contains a new requirement specifying that the general information needed to identify the device and its manufacturer, and communicate safety and performance related information to the users should be made avail-able on...	

	23.1 (e) Where multiple devices are supplied to a single user and/or location...		
		The focus of this requirement is on...	

Information on Label			
13.3 (a) the name or trade name and address of the manufacturer. For devices imported into the Commu-nity...	23.2 (d) if the manufacturer has its registered place of business outside the Union...	The Medical Device Directive allowed for the authorized EU representative to...	

Information on the sterile packaging			
	(a) an indication permitting the sterile packaging to be recognised as such,		
	...		