

Business Objective	Timely compliance with statutory and regulatory obligations ⁱ		
Date	2024		
< 5 Years			
Insert category of potentially affected area, e.g. financial, regulatory	High Impact If assessed as ‘High Impact’ provide detail available to date and potential impact	Medium Impact If assessed as ‘Medium Impact’ provide detail available to date and potential impact	Low Impact If assessed as ‘Low Impact’ provide detail available to date and potential impact
Compliance - The implementation of new European Union (EU) regulations, such as the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR).	<div>1. An increased administrative burden and potential delays in medical device availability can significantly affect healthcare delivery.</div> <div>2. Higher compliance costs may strain financial resources, particularly for smaller healthcare providers and suppliers.</div> <div>3. These regulations, aimed at improving patient safety and transparency, require comprehensive changes in compliance procedures, documentation, and reporting standards.</div>		
5 to 10 Years			
> 10 Years			

ⁱ This example is for illustration purposes only. It is provided solely as a guide for completing the template.