

Document V1000 Foetal Heart Simulator Labels Revision ID12017

Suggested Upload Document Name: **Risk Assesment For Updating Document ID12017**
Completed by [Catrin Hird](#) 08 Dec 2023

Reason for Risk Assesment

Contents updated from previous version, design file also required recreating due to previous provider no longer in business.

Document V1000 Foetal Heart Simulator Labels Revision ID12017 Is linked to the Following Standards and processes

test block		Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
Risk Assesment Question ID12017					
12017Q0	Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
12017Q1	Does V1000 Foetal Heart Simulator Technical file #66 Of type 1 require any Notificaions and/or Risk assesment updates due to this update	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
12017Q2	Final Notes				

SAVE FORM Only saves your progress in filling in above Questions - No feed back to pressing save form button
Once Form Complete Print Page to PDF (Landscape mode prefereable), go back to document upload page and upload to risk assesment button