

Document V1000 Foetal Heart Simulator Instructions for Use User Manual Operating Instructions (High) Revision ID16897

Suggested Upload Document Name: **Risk Assesment For Updating Document ID16897**
Completed by [Catrin Hird](#) 08 Sep 2023

Reason for Risk Assesment

305095 document update

Document V1000 Foetal Heart Simulator Instructions for Use User Manual Operating Instructions (High) Revision ID16897 Is linked to the Following Standards and processes

Risk Assesment Question ID16897	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
16897Q0 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 Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
16897Q1 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 Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
16897Q2 Final Notes				

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