

RISK ASSESSMENT

	Pass	Fail	n/a
<u>Mechanical</u>			
Structural strength	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Moving parts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trapping of fingers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Electrical</u>			
Mains voltage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low voltage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EMC - likely to be susceptible	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EMC - likely to cause interference	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Programmable system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Materials</u>			
Toxicity of materials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flammability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Corrosion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Interface with user</u>			
Sharp edges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risk of pressure sores	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vibration / noise	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High or low temperature	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Could be swallowed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>In use</u>			
Use in conjunction with other devices	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Operating instructions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Danger through misuse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Danger through incorrect assembly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The device:

- a) Has negligible risks when used for the purpose intended
- b) Has acceptable risks when used for the purpose intended
- c) Has unacceptable risks that need to be analysed in greater depth

Notes:.....

Signed Date

Photo taken? Labelled? Instructions? Database up-to-date?

DECLARATION (tick relevant statement)

- I confirm that the correct procedures have been followed and that the device is appropriate and safe for the use intended.
- I confirm that the device is a medical device, and conforms to the Essential Requirements of the medical devices directive.
- I confirm that the device is a medical device, and conforms to the Essential Requirements of the medical devices directive with the exceptions noted on the accompanying documentation.

Signed: **(Registered Clinical Scientist)**

Name:.....**Date**.....