

## Classification Rationale

Product Family	2160 SpO2		
Type	Rule	Class	Additional Information
Non-Invasive	Rule 1	11b	
Active	Rule 1 & 11		Monitors – SpO2
Invasive	No		
Special	No		

Flow chart includes: Yes or No

Classified by:  .....

Date: 01/10/2009

**The Device uses skin contact and is non-invasive.**

**It does not administer or exchange energy, fluids ,solids or gases. .**

**The 2160 is intended for use as a spot monitor for periods of not more than 60 Minutes**

**However it can be used for longer periods as it has 48hr trends.**

**The 2160 can be used in critical care areas**