

Classification Rationale

Product Family	21	2105 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: ...J.S.Lamb.....

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 2105 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 2105 can be used in critical care areas