

## Classification Rationale

Product/ Family			
Type	Rule	Class	Additional Information
Non-Invasive	Yes		
Active	Yes		Connected to oxygen regulator
Invasive	No		
Special	Yes Rule 9		Active therapeutic device used to “restore biological function in a potentially hazardous way”

BSI Flow chart included : Yes or No

Classified by: .....J. S Lamb.....

Date: 06...../...04...../...2018.....