

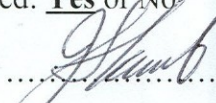
Classification Rationale.

Type	Rule	Class	Additional Information
Non-Invasive	Yes.	II b	
Active	Yes.		Connected to oxygen regulator.
Invasive	No		
Special	Yes, rule 9		Active therapeutic device used to "restore biological function" considered to be in a "potentially hazardous way".

BSI Flow chart included: Yes or No

Classified by:

Date:


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20 / 01 / 04