



## English EC Declaration of Conformity

We, **Gram Commercial A/S** declare under sole responsibility that the following products:

Name: **GRAM BioMidi (Accessory code 69)**  
Model: **RR 425 & 625**  
Refrigerant: **R134a, R404A & R290**

To which this declaration relates, is in compliance with all the applicable essential requirements, and other provisions of the European Council Directive.

### Directive of the European Parliament and of the Council:

- PED 2014/68/EU
- Directive for Machinery 2006/42/EU
- Low Voltage Directive 2014/35/EU
- RoHS 2011/65/EU

Product compliance has been demonstrated on the basis of:

| Harmonized Standards: | Text:   |
|-----------------------|---|
| DS/EN 60601-1: 2006   | Medical electrical equipment. General requirements for basic safety and essential performance.  |
| DS/EN 60601-1-2: 2015 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. |
| DS/EN 61010-1: 2010   | Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.   |
| DS/EN 60704-1: 2010   | Household and similar electrical appliances - Test code for the determination of airborne acoustical noise - Part 1: General requirements.  |
| DS/EN ISO 3744: 2010  | Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially free field over a reflecting plane.                        |
| DS/EN ISO 9001: 2015  | Quality management systems.   |
| DS/EN ISO 14001: 2015 | Environment management systems - Requirements with guidance for use.  |
| DIN 58345: 2007       | Refrigerators for drugs - Definitions, requirements, testing.   |
| DS/EN 50581: 2012     | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.   |

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