



## 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.

Gram Commercial A/S  
Aage Grams Vej 1  
DK-6500 Vojens  
Telephone: + 45 73 20 13 00

Vojens, 08.11.2018

John B. S. Petersen  
Approval Manager