



## English EC Declaration of Conformity

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

Name: **GRAM BioBlood**  
Model: 500, 600 D, 600 W, 660 D, 660 W, 930, 1270, 1400, PF 425, PF 600 W & PF 660 W  
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:

- ATEX Directive 2014/34/EU
- PED 2014/68/EU
- Low Voltage Directive 2014/35/EU
- EMC Directive 2014/30/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 60079-0: 2012	Electrical apparatus for explosive atmospheres.
DS/EN 60079-11: 2012	Explosive atmospheres – Part 11: Equipment protection by intrinsic safety 'i'.
DS/EN 60079-15: 2010	Explosive atmospheres – Part 15: Equipment protection by type of protection 'n'.
DS/EN 60079-25: 2010	Explosive atmospheres -- Part 25: Intrinsically safe electrical systems.
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
DS/EN 50581: 2012	Technical documentation for the assesment of electrical and eletronic products with respect to the restriction of hazardous substances.

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