English EC Declaration of Conformity

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

Name:	**GRAM BioBlood (Accessory code 69)**
Model:	**BR** 500, 600 D, 600 W, 660 D, 660 W, 930, 1270 & 1400
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 - 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 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	Enviroment management systems - Requirements with guidance for use
DIN 58371: 2010	Refrigerators for conserved blood - 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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