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, 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

Product compliance has been demonstrated on the basis of:

Harmonized Standards:	Text:
DS/EN 60601-1-1: 2005	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.
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: 2008	Quality management systems.

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

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John B. S. Petersen
Approval Manager