



## English EC Declaration of Conformity

We, **Gram Scientific ApS** declare under sole responsibility that the following products:

<b>Range:</b>	<b>BioBlood</b>
Model:	500, 600D, 600W, 660D, 660W, 930, 1270, 1400, PF425, PF600W & PF660W
Refrigeration:	R290, R404A & R134a
Product description:	Refrigerators and freezer for laboratory and biostorage
Valid from (Year/Week):	2023/01

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

### Directives and Regulations of the European Parliament and of the Council:

Machinery Directive 2006/42/EC  
- ATEX Directive 2014/34/EU  
- Pressure Equipment Directive 2014/68/EU  
- Low Voltage Directive 2014/35/EU  
- EMC Directive 2014/30/EU  
- RoHS Directive 2011/65/EU  
- REACH EC No.1907/2006  
- F-Gas Regulation (EU) No 517/2014

Product compliance has been demonstrated on the basis of:

Harmonized Standards:	Text:
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
EN 60601-1:2006	Medical electrical equipment. General requirements for basic safety and essential performance
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
EN 60079-0:2012	Electrical apparatus for explosive atmospheres – Part 0: General requirements
EN 60079-11:2012	Explosive atmospheres – Part 11: Equipment protection by intrinsic safety "i"
EN 60079-15:2010	Explosive atmospheres – Part 15: Equipment protection by type of protection "n"
EN 60079-25:2010	Explosive atmospheres – Part 25: Intrinsically safe systems
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
EN ISO 9001:2015	Quality management systems
EN ISO 14001:2015	Environment management systems – Requirements with guidance for use

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