



## English EC Declaration of Conformity

We, **Gram Scientific ApS**, declare as manufacturer under sole responsibility that the following products comply with all relevant regulations:

<b>Range:</b>	<b>BioBlood (Accessory code 69)</b>
Model:	PF425, PF600W & PF660W
Refrigeration:	R290 & R404A
Product description:	Freezer for laboratory and biostorage
Valid from (Year/Week):	2023/01

This declaration pertains to compliance with all applicable essential requirements and other provisions of the European Council Directive and regulations. Specifically, the following Directives and Regulations of the European Parliament and of the Council apply:

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

Machinery Directive 2006/42/EC  
- 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 2024/573

Product compliance has been demonstrated based on the following harmonized standards:

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 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
DIN 58375:2010	Plasma storage - Definitions, requirements, testing
EN ISO 9001:2015	Quality management systems
EN ISO 14001:2015	Environment management systems – Requirements with guidance for use

Gram Scientific ApS  
Aage Grams Vej 1  
DK-6500 Vojens  
Denmark  
Telephone: + 45 73 20 13 00

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John B. S. Petersen  
Approval Manager