



English EC Declaration of Conformity

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

Range:	BioBlood (Accessory code 69)
Model:	PF 425, 600W & 660W
Refrigeration:	R290 & R404A
Product description:	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
- 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 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

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