



English EC Declaration of Conformity

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

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|-------------------------|--|
| Range: | BioBlood |
| Model: | BR500, BF500, BR600D, BF600D, BR600W, BF600W, BR660D, BF660D, BR660W, BF660W, BR930, BF930, BR1270, BF1270, BR1400, BF1400, PF425, PF600W & PF660W |
| Refrigeration: | R290, R404A & R134a |
| Product description: | Refrigerators and 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
- 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 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 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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