



English EC Declaration of Conformity

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

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|-------------------------|--|
| Range: | BioBlood (Accessory code 69) |
| Model: | BR 500, 600D, 600W, 660D, 660W, 930, 1270 & 1400 |
| Refrigeration: | R290 & R134a |
| Product description: | Refrigerators 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 58371:2010 | Refrigerators for conserved blood – 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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