

## English EC Declaration of Conformity

We, Gram Commercial declare under sole responsibility that the following products:

Range: Model: Refrigeration: Product description: Valid from (Year/Week): **BioBlood (Accessory code 69) BR** 500, 600D, 600W, 660D, 660W, 930, 1270 & 1400 R290 & R134a Refrigerators for laboratory and biostorage 2022/02

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 -<br>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     | Enviroment management systems – Requirements with guidance for use   |

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

Vojens, 12.1.2022

Referse

John B. S. Petersen Approval Manager