



## English EC Declaration of Conformity

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

|                         |   |
|-------------------------|---|
| <b>Range:</b>           | <b>BioUltra</b>   |
| Model:                  | UL570   |
| Rerigerant:             | HC: R290 & R170 (R601 as additive)<br>HFC: R404A & R508B (R601 as additive) |
| Product description:    | Extreme low temperature freezers for storing biomedical materials           |
| 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  
- 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 517/2014

Product compliance has been demonstrated on the basis of:

| Harmonized Standards:                              | Text:   |
|--|---|
| EN 60601-1:2006                                    | Medical electrical equipment – Part 1: 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 disturbances – Requirements and tests   |
| EN 61010-1:2010                                    | Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements  |
| EN 61326-1:2013                                    | Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements  |
| EN IEC 61000-3-2:2019                              | Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current =16 A per phase)  |
| EN 61000-3-3:2013                                  | Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current <= 16 A per phase and not subject to conditional connection |
| EN IEC 60079-0:2018<br>EN IEC 60079-0:2018/AC:2020 | Explosive atmospheres – Part 0: Equipment – General requirements  |
| EN 60079-7:2015<br>EN 60079-7:2015/A1:2018         | Explosive atmospheres – Part 7: Equipment protection by increased safety "e"  |
| EN 60079-11:2012                                   | Explosive atmospheres – Part 11: Equipment protection by intrinsic safety "i"   |
| EN IEC 60079-15:2019                               | Explosive atmospheres – Part 15: Equipment protection by type of protection "n"   |
| EN 60079-18:2015                                   | Explosive atmospheres – Part 18: Equipment protection by encapsulation "m"  |
| EN ISO 3744:2010                                   | Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering methods for an essentially free field over a reflecting plane   |
| EN ISO 9001:2015                                   | Quality management systems – Requirements   |
| EN ISO 14001:2015                                  | Environmental management systems – Requirements with guidance for use   |

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Vojens, 13.12.2022

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