



English EC Declaration of Conformity

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

Range:	BioUltra
Model:	UL570
Rerigerant:	HC: R290 & R170 (R601 as additive) HFC: R404A & R508B (R601 as additive)
Product description:	Extreme low temperature freezers for storing biomedical materials
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 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 EN IEC 60079-0:2018/AC:2020	Explosive atmospheres – Part 0: Equipment – General requirements
EN 60079-7:2015 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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