



English EC Declaration of Conformity

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

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.
Serial number (Week/year):	04/2020 onwards

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:

- ATEX Directive 2014/34/EU
- Pressure Equipment Directive 2014/68/EU
- Directive for Machinery 2006/42/EU
- Low Voltage Directive 2014/35/EU
- EMC Directive 2014/30/EU
- RoHS 2011/65/EU
- REACH (EU) nr. 1907/2006
- Fluorinated greenhouse gases (EU) nr. 517/2014

Product compliance has been demonstrated on the basis of:

Harmonized Standards:	Text:
DS/EN 60601-1:2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
DS/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
DS/EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
DS/EN 61326-1: 2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
DS/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)
DS/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
DS/EN IEC 60079-0:2018 DS/EN IEC 60079-0:2018/AC:2020	Explosive atmospheres – Part 0: Equipment – General requirements
DS/EN 60079-7:2015 DS/EN 60079-7:2015/A1:2018	Explosive atmospheres – Part 7: Equipment protection by increased safety 'e'
DS/EN 60079-11:2012	Explosive atmospheres – Part 11: Equipment protection by intrinsic safety 'i'
DS/EN IEC 60079-15:2019	Explosive atmospheres – Part 15: Equipment protection by type of protection 'n'
DS/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
DS/EN ISO 9001:2015	Quality management systems – Requirements
DS/EN ISO 14001:2015	Environmental management systems – Requirements with guidance for use

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