



English EC Declaration of Conformity

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

Name: **GRAM BioUltra**
Model: **570**
Refrigerant: **R404A & R508B (R601 as additive)**

To which this declaration relates, is in compliance with all the applicable essential requirements, and other provisions of the European Council Directive.

Directive of the European Parliament and of the Council:

- PED 2014/68/EU
- Directive for Machinery 2006/42/EU
- Low Voltage Directive 2014/35/EU
- EMC Directive 2014/30/EU
- RoHS 2011/65/EU

Product compliance has been demonstrated on the basis of:

Harmonized Standards:	Text:
DS/EN 60601-1:2006	Medical electrical equipment. 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 compatibility - 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 ISO 9001:2015	Quality management systems.
DS/EN ISO 14001:2015	Environment management systems - Requirements with guidance for use
DS/EN 50581: 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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