English EC Declaration of Conformity

Name: Gram BioUltra
Model: UL570
Refrigerant: R404, R508 (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:
- Directive for Machinery 2006/42/EC - Low Voltage Directive 2006/95/EC - EMC Directive 2004/108/EC - RoHS 2002/95/EC

Product compliance has been demonstrated on the basis of:

Harmonized Standards:	Text:
EN 60601-1-1:2005	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
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 60601-1-6: 2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
DS/EN 61010-3: 2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
DS/EN ISO 13485: 2012	Medical devices - Quality management systems - Requirements for regulatory purposes

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Vojens, 25.11.2015

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