



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

Product compliance has been demonstrated on the basis of:

Harmonized Standards:	Text:
DS/EN 60601-1-1:2005	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.
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 9001:2008	Quality management systems.

Gram Commercial A/S
Aage Grams Vej 1
DK-6500 Vojens
Telephone: + 45 73 20 13 00

Vojens, 05.10.2016

John B. S. Petersen
Approval Manager