



English EC Declaration of Conformity

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

Range:	BioCompact II (Accessorie code 69)
Model:	210, 310, 410, 210/210 & 310/210
Refrigeration:	R600a & R134a
Product description:	Refrigerators and freezer for laboratory and biostorage
Valid from (Year/Week):	2023/01

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:

Machinery Directive 2006/42/EC
- 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 517/2014

Product compliance has been demonstrated on the basis of:

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
DIN 58345:2007	Refrigerators for drugs – Definitions, requirements, testing
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

Gram Scientific ApS
Aage Grams Vej 1
DK-6500 Vojs
Denmark
Telephone: + 45 73 20 13 00

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John B. S. Petersen
Approval Manager