

**1 ATEX CAT 3G Conformity Certificate**

2 Equipment intended for use in Potentially Explosive Atmospheres Directive 2014/34/EU

3 Certificate Number: ExVeritas 26 ATEX 2340 X Issue: 0

4 Type:: Freezers

Model: BioUltra

Variant: UL570 series (see type key under item 15)

5 Manufacturer: Gram Scientific ApS

6 Address: Aage Grams Vej 1  
6500 Vojens  
Denmark

7 This equipment and any acceptable variation thereto are specified in the schedule to this certificate and the documents therein referred to. The assessments are recorded in ExVeritas project file number EXV5958A.

8 The equipment has been assessed against the following Standards and found to comply:

EN IEC 60079-0: 2018

EN 60079-7:2015/A1:2018

EN 60079-11: 2012

9 If the sign "X" is placed after the certificate number, it indicates that the equipment is subject to special conditions for safe use specified in the schedule to this certificate.

10 This assessment is based on information and data supplied by the manufacturer. Information has been reviewed by ExVeritas as part of the conformity assessment process. Responsibility for the accuracy and completeness of this data remains with the manufacturer.

11 The marking of the equipment shall include the following:

 II 3 G Ex ec ic IIB T4 Gc

On behalf of ExVeritas



Peter Lauritzen  
Managing Director

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## Schedule

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### Description of Equipment or Protective System

The BioUltra model comprises ultra-low temperature freezers intended for use in hospitals, laboratories, biobanks, research facilities, and similar applications requiring secure storage of biological materials, industrial samples, and other temperature-sensitive products within the range of -60 °C to -86 °C, at ambient conditions of +10 °C to +30 °C.

The units are equipped with a bottom-mounted cascade refrigeration system to ensure stable and efficient temperature control. Thermal insulation is provided by vacuum insulated panel (VIP) technology, supporting low energy consumption and consistent temperature performance. The door system incorporates a multi-layer gasket arrangement integrated into a labyrinth frame design, ensuring secure sealing and minimizing thermal loss during operation.

#### Variants covered by this certificate:

The BioUltra can be delivered in several variants with different types of options and accessories. The basic version is an air-cooled unit BioUltra UL 570, 230 V/50 Hz compressor with refrigerant: R290/R170 - R601 or R404A/R508 - R601 (only outside EU)

|                   |                      |               |
|-------------------|----------------------|---------------|
| Cabinet           | 570                  |               |
| Model/Variant     | BioUltra UL570(10..) |               |
| Refrigerant       | HC                   | HFC           |
| Connection        | 230V/50 Hz           | 230V/50-60 Hz |
| Temperature Class | T4                   | T4            |

The variant number system is specified to the following concept:

#### BioUltra UL570 yx zz

Where "zz" are defined in a sequence (no space in between) of the below listed equipment variants. (e.g. BioUltra UL570 CG 1020294178)

|                   |                                         |
|-------------------|-----------------------------------------|
| BioUltra UL570    |                                         |
| Temperature range |                                         |
| UL                | -60/86°C                                |
| Refrigerant (x)   |                                         |
| H                 | R404A/R508 – R601 (only outside EU)     |
| G                 | R209/R170 – R601                        |
| Exterior (zz)     |                                         |
| C                 | Stainless Steel                         |
| L                 | White Lacquered                         |
| Equipment (zz)    |                                         |
| 10                | Solid door                              |
| 12                | Customized door                         |
| 15                | RUKO lock (DK)                          |
| 20                | Right hinged incl. self-closing         |
| 21                | Left hinged incl. self-closing          |
| 22                | Right hinged                            |
| 23                | Left hinged                             |
| 29                | Levelling castors                       |
| 41                | E-sensor                                |
| 42                | Customized sensor*                      |
| 72                | Insulated inner doors (2 doors)         |
| 78                | Water cooled condenser (only HFC)       |
| 79                | Hybrid – water and fan cooled condenser |
| 82                | 60 Hz compressor                        |

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|     |                                     |
|-----|-------------------------------------|
| ..V | # of liquid containers incl. Holder |
| ..P | # of perforated shelves             |

Only type variants listed in the table above are covered by this certification.

Specified ambient temperature:  $+10\text{ °C} < T_{amb} < +30\text{ °C}$

Ingres Protection : IP 2X

## 13 Descriptive Documents

### 13.1 Associated Report and Certificate History:

| Report Number | Cert Issue Date | Issue | Comment                                |
|---------------|-----------------|-------|----------------------------------------|
| 5958/A/1      | 2026-09-02      | 0     | Initial issue of the Prime Certificate |

### 13.2 Compliance Drawings:

#### Issue 0

| Title:                                  | Drawing No:                                                          | Issue: | Date:      |
|-----------------------------------------|----------------------------------------------------------------------|--------|------------|
| Product Description                     | 2026-05-01_Description_of_BioUltra_UL570_Rev006                      | 006    | 2026-06-04 |
| Description of PE / bonding connections | 2020-04-15_Ex16-2020_Bonding_BioUltra_Rev001                         | 001    | 2020-04-15 |
| Instructions for use                    | 765041576_20260107_BioUltra_INSTRUCTIONS_FOR_USE-web-English         |        | 2026-07-01 |
| Determination of temperature classes    | 2026-05-27_Ex94-2026_BioUltra_Temperature_class_determination_Rev001 | 001    | 2026-05-27 |

## 14 Conditions of Certification

### 14.1 Special Conditions for Safe Use

1. The power supply to the freezers is through a plug/socket connection on the electronic control box. The manufacturer delivers the belonging supply cable. The locking mechanism on the plug/socket connection must always be used. The supply cord/plug must only be connected in a non-hazardous area. If the freezers are electrically connected in a zone classified area, the supply cord must be connected in a terminal box complying with national installation requirements e.g. EN 60079-14.
2. To secure potential equalization of the unit – the mounted external bonding/ground connector must be used in accordance with national installation requirements e.g. EN 60079-14.
3. The specified ambient temperature for "BioUltra" freezers are limited to:  $+10\text{ °C} < T_{amb} < +30\text{ °C}$
4. The equipment shall only be used in an area of at least pollution degree 2, as defined in IEC 60664-1 (Indoor laboratories / Office environment).
5. Transient protection shall be provided that is set at a level not exceeding 140% of the peak rated voltage value at the supply terminals to the equipment.

### 14.2 Conditions of manufacture (Routine Tests)

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### **Schedule**

#### Essential Health and Safety Requirements

Essential Health and Safety Requirements are addressed by the standards listed in section 8 and where required the report listed in section 13.1

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