

EC CERTIFICATE Production Quality Assurance

Certificate No.: 10000448399-PA-NA-NOR

Project No.: PRJC-519733-2015-MSL-NOR_MDD Valid Until: 27 May 2024

This is to certify that the quality system of:

Arctiko

Oddesundvej 39, Esbjerg N, 6715 Denmark

For production and final product inspection/testing of:

Blood bank refrigerators

Has been assessed with respect to:

The conformity assessment procedure described in Annex V of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date: Høvik, 20 May 2021 For the issuing office:
Notified Body 2460
DNV Product Assurance AS



Mariann Jeremiassen Principal Assessor



Certificate No.: 10000448399-PA-NA-NOR Place and date: Høvik, 20 May 2021

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

| Revision | Description | Issue Date |
|----------|----------------------|------------|
| 0.0 | Original Certificate | 2021-05-20 |

Products covered by this Certificate:

| Product Description | Product Name | Class |
|--------------------------|---|-------|
| Blood bank refrigerators | BBR100, BBR300, BBR500, BBR700, BR1400, BBR100-D, BBR300-D, BBR500-D, BBR700-D, BBR1400-D | Ila |

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

| Site Name | Address |
|-----------|---|
| Arctiko | Oddesundvej 39, Esbjerg N, 6715 Denmark |



Certificate No.: 10000448399-PA-NA-NOR Place and date: Høvik, 20 May 2021

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a
 defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning
 liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 10000320341-PA-NA-NOR

Project No.: PRJC-519733-2015-MSL-NOR Initial Certification Date: 05 December 2019

Valid Until: 04 December 2022

This is to certify that the management system of:

Arctiko A/S

Oddesundvej 39, 6715 Esbjerg N, Denmark

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

DESIGN, DEVELOPMENT, MANUFACTURING, SALES AND SERVICES OF REFRIGERATORS AND FREEZERS CLASSIFIED AS MEDICAL DEVICES.

Place and date: Høvik, 05 December 2019



MSYS 018

DNV GL PRESAFE AS

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

ACCREDITED UNIT: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høyik, Norway - Registered Enterprise No: NO 997 067 401 MVA

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LFF 270

SMART FRIDGE AND FREEZER IN ONE CABINET, MAKES IT A PERFECT SOLUTION FOR LABORATORIES WITH LIMITED SPACE DUE TO THE SMALL FOOTPRINT.

With air forced cooling and automatic defrost which will save time to focus on what's most important and store the samples most reliable.







FILTERLESS

INDEPENDENT & LESS FOOTPRINT

The LFF comes with two controllers allowing you to set and operate them as two independent units. With separate locks and passwords, it provides the ability to restrict access to storage and settings, in case the unit have multiple users. The unit is in effect of two fully independent units each with its own compressor, cooling circuit and controller - allowing to turn off one of the compartments in case that they are not in use for some time.

STAINLESS STEEL & AUTOMATIC DEFROST

The unit is available with stainless steel AISI 304 Exterior, so that the interior and exterior is made entirely of stainless steel, providing a stronger more resistant unit.

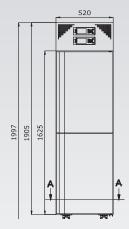
With Arctiko's automatic defrost system it's not required to remove samples prior to defrosting, saving you valuable time to focus on what matter the most and at the same time stores the samples safely.

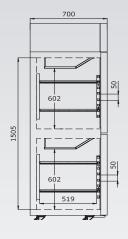
EXCEPTIONAL COOLING

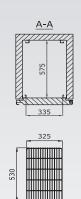
Arctiko has combined the high quality cooling performance created by air-forced cooling and automatic defrosting.

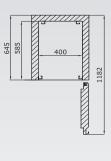
The results meet the more stringent requirements for lower power consumption, more precise cooling uniformity, need for temperature and alarm surveillance, documentation and validation, making the LFF 270 the perfect solution for biomedical storage.

MAIN DIMENSION FOR LFF 270









MAIN SPECIFICATIONS

| Item code | DAI 0235 / DAI 0236 |
|--------------------------------|---------------------|
| Temperature range (°C) | +1 / +10 -10 / -30 |
| Max. ambient temperature (°C) | 32 |
| Capacity (L) | 161 / 161 |
| Exterior dimensions WxDxH (mm) | 520x700x1997 |
| Interior dimensions WxDxH (mm) | 2x(400x575x700) |
| Weight (KG) | 120 |
| Insulation (mm) | 60 |
| Cooling technology | air forced |
| Controller model / probe type | G214 / PT1000 |

POWER

| Power supply (V) | 230* |
|-----------------------------|------------|
| Frequency (Hz) | 50/60 |
| Power consumption (kWh/24H) | 11,4 |
| AMP (A) | 5,8 |
| Power (Watt) | 728 |
| Horse power (HP) | 1/10 + 1/8 |

ALARM FUNCTIONS

| Alarm display as text - not codes | yes |
|--|-----------|
| Visual / acoustic alarm | yes / yes |
| Power failure alarm | yes |
| Adjustable high / low temperature alarm | yes / yes |
| Open door alarm | yes |
| Probe failure alarm | yes |
| Low battery alarm | yes |
| Compressor failure alarm | no |
| Battery backup for alarms (approx. hrs.) | 72 |

DATA LOGGING & EXTERNAL CONNECTION

| Voltage free contact for remote alarm (e.g. GSM alarm module) | yes |
|---|----------|
| Electronic data logger | yes |
| RS 485 port | yes |
| USB port for software update & data download | yes |
| Temperature chart recorder | optional |

DISPLAY FEATURES

| Display type | 4,3" with touch buttons |
|---|-------------------------|
| Number of optional reference probes | 2 |
| Password protection for turning unit on / off | yes |
| Temperature graph on display | yes |

OTHER FEATURES

| Automatic defrost | yes |
|---|----------|
| Antifreeze function | no |
| Vacuum release port | no |
| Access port for external probe etc. (int. diameter mm) | optional |
| Light | no |
| Lock with key | yes |
| Castors (total pcs) / castors with brake (pcs) | 4/2 |
| Fixed feet (pcs) / levelling feet (pcs) | no |
| Sub lids or inner doors (pcs) | no |
| Reversible door(s) | yes |
| Fixed shelves (pcs) / adjustable shelves (pcs) | 0 / 4 |
| Max. no. of shelves (pcs) / recommended max. no. of shelves (pcs) | 16 / 8 |
| Max. load per shelf (kg) | 30 |
| Adjustable drawers (pcs) | optional |
| Max. no. of adjustable drawers (pcs) | 6 |
| Max load per adjustable drawer (kg) | 30 |

REFRIGERATION & CABINET

| Number of compressors | 2 |
|-----------------------------|---------------------------------|
| Refrigerant | R290 |
| Interior cabinet material | stainless steel |
| Exterior cabinet material | painted steel / stainless steel |
| Colour (exterior cabinet) | white / stainless steel |
| Foam type | polyurethane |
| VIP vacuum insulated panels | no |

SHIPPING

| Shipping weight (KG) | 175 |
|--------------------------------|-----------|
| Shipping dimensions WxDxH (cm) | 83x67x220 |
| Shipping volume (m³) | 1.22 |

^{*110}V/60Hz available as option

OPTIONAL ACCESSORIES

GSM alarm module
Temperature chart recorder
Shelves (perforated, wire stainless
steel, plastic coated)
Drawers (stainless steel)
Modbus adapter
Voltage stabilizer
Voltage converters
LED light





