



Product Service

Certificate

No. Q5 031461 0039 Rev. 01

Holder of Certificate: **BMT Medical Technology s.r.o**

Cejl 157/50
60200 Brno - Zábřovice
CZECH REPUBLIC

Facility(ies):

BMT Medical Technology s.r.o
Cejl 157/50, 60200 Brno - Zábřovice, CZECH REPUBLIC

Certification Mark:



Scope of Certificate:

Design and development, production, distribution, installation and service of medical systems for sterilization and disinfection

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

713155414

Valid from:

2019-08-01

Valid until:

2022-07-31

Date,

2019-07-16

Stefan Preiß

Head of Certification/Notified Body



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

BMT Medical Technology s.r.o.

**Cejl 157/50
602 00 Brno - Zábřovice
Czech Republic**

has established and applies
a Quality Management System for

**Design and Development, production and distribution of
products used in healthcare, research institutes, laboratories
and industry in particular sterilizers, incubators,
drying, cooling and heating ovens.**

An audit was performed, Order No. **70074721**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2019-08-01** until **2022-07-31**.

Certificate Registration No.: **12 100 24021 TMS**.

Product Compliance Management
Munich, 2019-07-23



ZERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆
CERTIFIKAT ◆ CERTIFICATE ◆ CERTIFICADO ◆ CERTIFICAT ◆
認證書 ◆



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 031461 0036 Rev. 01

Manufacturer: **BMT Medical Technology s.r.o**
Cejl 157/50
60200 Brno - Zábřovice
CZECH REPUBLIC

Facility(ies): BMT Medical Technology s.r.o
Cejl 157/50, 60200 Brno - Zábřovice, CZECH REPUBLIC

Product Category(ies): **Devices for Sterilization and
Disinfection in Health Care Facilities**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713164034

Valid from: 2020-01-08
Valid until: 2024-05-26

Date, 2020-01-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

Zertifizierungsvertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifizierungssystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations. On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

- Validity of the quoted test standard(s) In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约

认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：

- 认证所依据标准的有效性
- 此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
 - 生产场地通过定期的监督

認証契約

認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項

- 引用している試験規格が有効である
- さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
 - 定期的な工場監査を実施している

Contrato de certificação

A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD. Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):

- Validade da(s) norma(s) de ensaio(s) referenciada(s).
- Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
 - Auditoria de monitoração realizada regularmente.



elmi Ltd.
laboratory equipment



ISO 9001:2000



CE CONFORMITY DECLARATION

The undersigned ELMI Ltd. company declares, that the following instrument(s) conforms the bellow mentioned directives and standards:

| | |
|-----------------|---|
| Manufacturer: | ELMI Ltd. Aizkraukles str. 21-136, Riga LV-1006, Latvia Phone: (+371) 67558 743 Fax: (+371) 67551 934 |
| Equipment name: | CM-50, CM-6M, CM-6MT, CM-70, CM-70M, CM70M.07, CM70M.09, CM70M.12 |
| Equipment type: | Laboratory centrifuge |
| Directives: | EMC Directive 89/336/EEC "ELECTROMAGNETIC COMPATIBILITY" LVD Directive 73/23/EEC "ELECTRICAL EQUIPMENT DESIGNED FOR USE WITHIN CERTAIN VOLTAGE LIMITS" |

| | |
|---|---|
| Applied standards: Harmonized standards: | EN 61326: Electrical equipment for measurement, Control and laboratory use - EMC requirements Part 1: General requirements EN 61010: Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements Part 2-20: Particular requirements for laboratory centrifuges. |
|---|---|

Ivan Mironov, President,
ELMI Ltd.



Nikolay Truhan,
Technical Director

ELMI Ltd.

Aizkraukles str. 21-136, Riga LV-1006, Latvia
Phone: (+371) 67558 743 Fax: (+371) 67551 934
Web: www.elmi-tech.com E-mail: info@elmi-tech.com



DECLARATION OF CONFORMITY

The undersigned ELMI SIA company declares, that the following instrument(s) conforms the below mentioned directives and standards:

| | |
|-----------------|---|
| Manufacturer: | ELMI SIA Krīvu street 11-136, Riga LV-1006, Latvia Phone: (+371) 67558 743 Fax: (+371) 67551 934 |
| Equipment name: | S3, S-3M.A02, S-3M.A10, S-3M.A20, S-3L.A10, S-3L.A20, S-3.02M.A10, S-3.02M.A20, S-3.02L.A10, S-3.02L.A20, S-4 |
| Equipment type: | Orbital Shaker |
| Directives: | EMC Directive 2004/108/EC Low Voltage Directive 2006/95/EC RoHS 2011/65/EC WEEE 2002/96/EC & 2012/19/EU In vitro diagnostic medical devices directive 98/79/EC, Annex III |

| | |
|--------------------|---|
| Applied standards: | <u>EN 61326-1: 2013</u> Electrical equipment for measurement, control and laboratory use EMC requirements. General requirements. <u>EN 61010-1: 2010</u> Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements. <u>EN 61010-2-051: 2015</u> Particular requirements for laboratory equipment for mixing and stirring. |
|--------------------|---|

Vitalijs Mironovs
Technical Director

Maksims Sviridovs
Manufacturing Director



30.04.2019
Date

30.04.2019
Date

DECLARACIÓN UE DE CONFORMIDAD EU DECLARATION OF CONFORMITY



Esta declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante
This declaration of conformity is issued under the sole responsibility of the manufacturer

El siguiente equipo cumple con todos los requisitos esenciales para la salud y seguridad de las Directivas Europeas.
The following machinery complies with all the essential health and safety requirements of the European Directives

| | |
|-------------------------------------|---|
| Descripción - Description of device | CENTRÍFUGA DE LABORATORIO /CENTRIFUGE FOR LABORATORY |
| Marca - Trade Mark: | ORTOALRESA |
| Modelo - Model: | LACTER 21 |
| Tipo - Type | CE 158 / CE 159 |

Directivas Europeas. European Directives:

Directiva relativa a las máquinas 2006/42/CE.
Directive on machinery 2006/42/EC.

Directiva de comercialización de material eléctrico destinado a utilizarse con determinados límites de tensión 2014/35/UE.
Directive on the market of electrical equipment designed for use within certain voltage limits 2014/35/EU.

Directiva de compatibilidad electromagnética 2014/30/UE.
Directive to electromagnetic compatibility 2014/30/EU.

Directiva sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos (RoHS) 2011/65/UE.
Directive related to the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) 2011/65/EU.

Directiva sobre residuos aparatos eléctricos y electrónicos (RAEE) 2012/19/UE.
Directive on waste electrical and electronic equipment (WEEE) 2012/19/EU.

The object of the declaration described above is in conformity with the relevant Union harmonization legislation.
El objeto de la declaración descrita anteriormente está en conformidad con la legislación de armonización de la Unión pertinente.

Normas armonizadas aplicadas. Applied harmonized standards

EN 61010-1 EN 61010-2-010 EN 62321-1

EN 61010-2-020 EN 61326-1

Los ensayos de las normas están certificados por laboratorio acreditado.
The tests of the norms are certified for accreditation laboratory.

En Daganzo a 31 de octubre de 2019

J.A. ALVAREZ GONZALEZ
Gerente/Manager

EU Declaration of Conformity

We Glen Dimplex Medical Appliances
Of Stoney Lane, Prescot, Merseyside, L35 2XW, UK

In accordance with the following Directive(s):

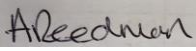
2014/35/EU The Low Voltage Directive
2014/30/EU The Electromagnetic Compatibility Directive
2011/65/EU Restriction of the use of certain Hazardous Substances in electrical and electronic equipment
2014/34/EU Equipment and protective systems intended for use in potentially explosive atmospheres

Hereby declare that:

The Refrigerators listed on page 2 are in conformity with the applicable requirements of the following documents

| <u>Ref No.</u> | <u>Title</u> | <u>Edition/date</u> |
|----------------|--|----------------------------|
| IEC 60335-1 | Household and similar electrical appliances. Safety. General requirements | 2010 + A1:2013 +A2:2016 |
| IEC 60335-2-24 | Household and similar electrical appliances. Requirements for refrigerating appliances, ice cream appliances and ice makers | 2010 +A1: 2012 +A2:2017 |
| EN 61010-1 | Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements | 2010 |
| EN 55014-1 | Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Emission | 2017 |
| EN 55014-2 | Electromagnetic compatibility. Requirements for household appliances, electric tools and similar apparatus. Immunity. Product family standard. | 2015 |
| IEC 61000-3-2 | Mains harmonics, Class A | 2014 |
| IEC 61000-3-3 | Mains voltage flicker (dmax=4%) | 2013 |
| EN 50581 | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances | 2012 |

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directives.

Signed: 

Name: Andrew Reedman
Position: Technical Manager
Location: Glen Dimplex Medical Appliances, Prescot
On: 13th Jan 2020 Issue 6



Document Reference No.
Cold Appliances - GDMA

| Stock Number | Model | Appliance Type | Stock Number | Model | Appliance Type |
|-------------------------|---------------|----------------|--------------|-----------------|----------------|
| Pharmacy models: | | | | | |
| 444410526 | PPSR158UK | Fridge | 444410569 | PESR47UK Boots | Fridge |
| 444410568 | PESR47UK | Fridge | 444410527 | PPGR158UK | Fridge |
| 444410566 | PESR158AU | Fridge | 444410567 | PEGR158AU | Fridge |
| 444410651 | PPSR273UK | Fridge | 444410657 | PEGR273AU | Fridge |
| 444410629 | PESR107UK | Fridge | 444410630 | PEGR107UK | Fridge |
| 444410631 | PEGR107UK-LHH | Fridge | 444410634 | PESR107EU | Fridge |
| 444410635 | PEGR107EU | Fridge | 444410638 | PESR41UK | Fridge |
| 444410639 | PEGR41UK | Fridge | 444410640 | PESR82UK | Fridge |
| 444410641 | PEGR82UK | Fridge | 444410644 | PESR41EU | Fridge |
| 444410645 | PEGR41EU | Fridge | 444410646 | PESR82EU | Fridge |
| 444410647 | PEGR82EU | Fridge | 444410649 | PESR82TROP | Fridge |
| 444410650 | PEGR82TROP | Fridge | 444410571 | PESR47UK Lloyds | Fridge |
| 444410528 | PPGR158UK-LHH | Fridge | 444410540 | PPGR158EU | Fridge |
| 444410539 | PPSR158EU | Fridge | 444410530 | PPSR158UK-DWP | Fridge |
| 444410531 | PPGR158UK-DWP | Fridge | 444410559 | PPSR158UK-DLK | Fridge |
| 444410560 | PPGR158UK-DLK | Fridge | 444410652 | PPGR273UK | Fridge |
| 444410570 | PPSR47UK | Fridge | 444410576 | PPSR47EU | Fridge |
| 444410528 | PPGR158UK-LHH | Fridge | 444410539 | PPSR158EU | Fridge |
| 444410656 | PESR273AU | Fridge | 444410658 | PPSR273EU | Fridge |
| 444410659 | PPGR273EU | Fridge | 444410665 | PPGR353UK | Fridge |
| 444410666 | PPSR353UK | Fridge | 444410668 | PPGR353EU | Fridge |
| 444410669 | PPSR353EU | Fridge | 444410670 | PESR353AU | Fridge |
| 444410671 | PEGR353AU | Fridge | | | |

| Ward models: | | | | | |
|---------------------|-----------|--------|-----------|---------|--------|
| 444410660 | WSR288CUK | Fridge | 444410642 | WSR82UK | Fridge |
| 444410536 | WSR158UK | Fridge | | | |

| Laboratory models: | | | | | |
|---------------------------|------------|---------|-----------|------------|---------|
| 444410574 | LSFSF39UK | Freezer | 444410672 | LSFSF232UK | Freezer |
| 444410632 | LSFSR107UK | Fridge | 444410633 | LSFSF107UK | Fridge |
| 444410636 | LSFSR107EU | Fridge | 444410637 | LSFSF107EU | Freezer |
| 444410643 | LSFSR82UK | Fridge | 444410648 | LSFSR82EU | Fridge |
| 444410534 | LSFSR158UK | Fridge | 444410535 | LSFSF98UK | Fridge |
| 444410542 | LSFSR158EU | Fridge | 444410543 | LSFSF98EU | Freezer |
| 444410661 | LSFSR288UK | Fridge | 444410674 | LSFSF232EU | Fridge |

| | | | | | |
|-----------|-----------------|---------|-----------|-----------------|---------|
| 444410577 | LSFSF39EU | Freezer | 444410557 | LSFSF98UK-ATEX | Freezer |
| 444410558 | LSFSR158UK-ATEX | Fridge | 444410662 | LSFSR288UK-ATEX | Fridge |
| 444410675 | LSFSF232EU-ATEX | Freezer | 444410676 | LSFC263UK | Combi |
| 444410677 | LSFC263UK-ATEX | Combi | 444410679 | LSFC263EU | Fridge |
| 444410680 | LSFC324UK | Combi | 444410637 | LSFSF107EU | Freezer |
| 444440367 | PSR600UK | Fridge | 444442593 | PSR600EU | Fridge |
| 444440365 | PGR600UK | Fridge | 444442591 | PGR600EU | Fridge |
| 444440368 | PSR1200UK | Fridge | 444442594 | PSR1200EU | Fridge |
| 444410684 | LSFC119UK | Combi | | | |
| | | | | | |

| Staff Room models: | | | | | |
|--------------------|---------|--------|--|--|--|
| 444410537 | SRS158W | Fridge | | | |
| | | | | | |
| | | | | | |

| Issue | Description | Date |
|-------|--|----------|
| 1 | Document Released (444410526 / 444410569) | 28/11/18 |
| 2 | Add: 444410568 / 444410527 / 444410566 / 444410567 / 444410651 / 444410657 / 444410660 / 444410574 / 444410672 | 20/12/18 |
| 3 | Add: 444410629/10630/10631/10632/10633/10634/10635/10636/10637/10638/10639/10640/10641/10642/10643/10644/10645/10646/10647/10648/10649/10650 | 30/01/19 |
| 4 | Add: 444410571, 10528, 10540, 10539, 10530, 10531, 10559, 10560, 10652, 10536, 10534, 10535, 10542, 10543, 10661, 10674, | 28/3/19 |
| 5 | Add: 444410577, 10570, 10576, 10557, 10528, 10539, 10565, 10658, 10662, 10665, 10666, 10668, 10669, 10670, 10671, 10675, 10676, 10677, 10680, 10637, 10537 | 11/09/19 |
| 6 | Add: 444440367, 2593, 0365, 2591, 0368, 2594, 0684 | 13/01/20 |
| | | |
| | | |
| | | |



CERTIFICATO

Nr. 50 100 8666 - Rev.003

Si attesta che / This is to certify that

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

OPTIKA S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA RIGLA 30
IT - 24010 PONTERANICA (BG)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione, ricerca e sviluppo, fabbricazione, controllo qualità ed assistenza tecnica relativamente a strumentazione scientifica, microscopi ottici ed accessori (IAF 19)

Design, research and development, manufacture, quality control and technical assistance related to scientific instrumentation, microscopes and accessories (IAF 19)



SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, WF e ILAC
Signatory of EA, WF and ILAC Mutual
Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body

TÜV Italia S.r.l.

Validità / Validity

Dal / From: 2018-04-25

Al / To: 2021-04-24

Data emissione / Printing Date

Andrea Coscia

Direttore Divisione Business Assurance

2018-03-18

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2009-04-24

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Glen Dimplex Home Appliances Limited
Stoney Lane
Rainhill
Prescot
L35 2XW
United Kingdom

Holds Certificate Number:

FM 25534

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The design, manufacture, sourcing, service, repair, product re-work and supply of free standing or built-in gas, electric and dual-fuelled (gas/electric) cooking appliances.
The design, manufacture, service, repair and supply of (gas/electric) water heaters.
The sourcing, product re-work and supply of (gas / electrical) appliances.
The design and manufacture of commercial refrigeration equipment.

For and on behalf of BSI:



Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 1993-09-01

Latest Revision Date: 2019-01-30

Effective Date: 2019-02-06

Expiry Date: 2022-02-05



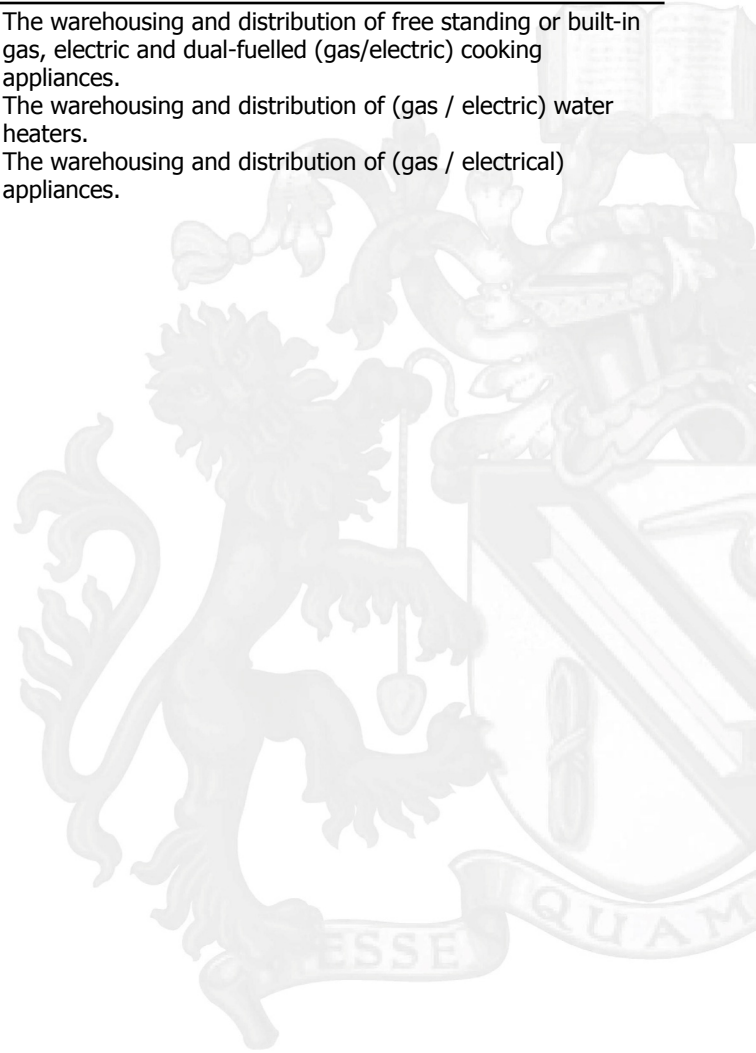
003

Page: 1 of 2

...making excellence a habit.™

Certificate No: FM 25534

| Location | Registered Activities |
|---|--|
| Glen Dimplex Home Appliances Limited Stoney Lane Rainhill Prescot L35 2XW United Kingdom | The design, manufacture, sourcing, service, repair, product re-work and supply of free standing or built-in gas, electric and dual-fuelled (gas/electric) cooking appliances. The design, manufacture, service, repair and supply of (gas/electric) water heaters. The sourcing, product re-work and supply of (gas / electrical) appliances. The design and manufacture of commercial refrigeration equipment. |
| Glen Dimplex Home Appliances National Distribution Centre Eastern Rise Off Stanley Matthews Way Stoke-on-Trent ST4 8WG United Kingdom | The warehousing and distribution of free standing or built-in gas, electric and dual-fuelled (gas/electric) cooking appliances. The warehousing and distribution of (gas / electric) water heaters. The warehousing and distribution of (gas / electrical) appliances. |



Original Registration Date: 1993-09-01

Latest Revision Date: 2019-01-30

Effective Date: 2019-02-06

Expiry Date: 2022-02-05

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

EU DECLARATION OF CONFORMITY

Manufacturer: OPTIKA SRL
Address: Via Rigla, 30
ZIP Code, City, Country: 24010, Ponteranica (BG), Italy

WE

DECLARE UNDER OUR OWN SOLE RESPONSIBILITY THAT THE PRODUCTS:

DESCRIPTION: MICROSCOPES

SERIES: B-190

MODELS: B-191 - B-191s - B-192 - B-192s - B-193 - B-190TB

**are in conformity with Directive 2011/65/EU of the European Parliament
and of the Council of 8 June 2011 on the restriction of the use of certain
hazardous substances in electrical and electronic equipment**

AND

ARE IN CONFORMITY TO THE ESSENTIAL REQUIREMENTS OF THE FOLLOWING DIRECTIVES

2014/30/EU

on electromagnetic compatibility

2014/35/EU

on low voltage equipment

VERIFIED USING, WHERE APPLICABLE, THE HARMONIZED STANDARDS

EN55015: 2013

EN61547: 2009

EN61010-1:2010

EN61000-3-2: 2014

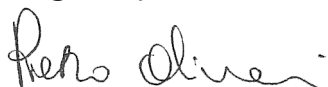
EN61000-3-3: 2013

AND ALL OTHER APPLICABLE SPECIFICATIONS

PONTERANICA, 15th February, 2016

SIGNED FOR ON BEHALF OF THE MANUFACTURER:

OPTIKA SRL
Pietro Oliveri
Legal Representative



VWR International S.r.l.
Via San Giusto, 85
20153 Milano - Italia
t 02 3320311

CONFORMITY DECLARATION TO ELECTRICAL STANDARDS

DICHIARAZIONE DI CONFORMITÀ AGLI STANDARD ELETTRICI

We herewith confirm that the following product manufactured and tested by VWR International s.r.l. Via San Giusto 85, 20153 Milano, Italy

Con la presente si dichiara che il seguente prodotto realizzato e testato da VWR International s.r.l. Via San Giusto 85, 20153 Milano, Italia

SAS SUPER

(Article number: 710-0866, 710-0867, 710-0868, 710-0869, 710-0870, 710-0871, 710-0872, 710-0919, 710-0943, 710-0944, 710-0945, 710-0946)

SAS SUPER

(Article number: 710-0866, 710-0867, 710-0868, 710-0869, 710-0870, 710-0871, 710-0872, 710-0919, 710-0943, 710-0944, 710-0945, 710-0946)

complies with the following

DIRECTIVES

- 2004/108/EC

STANDARDS

- EN 61326-1: 2006
- EN 55011: 2007

è conforme a quanto segue

DIRETTIVE

- 2004/108/EC

STANDARD

- EN 61326-1: 2006
- EN 55011: 2007

Date of issue
Data di emissione

07.02.2020

Signature
Firma



Antonio Maconi
Managing and Finance Director

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY
DÉCLARATION DE CONFORMITÉ CE

El fabricante | The manufacturer | Le fournisseur: AUXILAB, S.L.

Declara que el equipo | Declare that the equipment | Declare que l'appareil:
Evaporador rotativo RS 100-PRO; Evaporador rotativo RS 100-PRO, recubierto; Evaporador rotativo RS100-S
| Rotary evaporator RS 100-PRO; Rotary evaporator RS 100-PRO, coated; Rotary evaporator RS100-S |
Evaporateur rotatif RS 100-PRO; Evaporateur rotatif RS 100-PRO, gainé; Evaporateur rotatif RS100-S

Código | Code | Référence: PGB006, PGB007, PGB009

Cumple con las siguientes directivas | Meet the following directives | Accomplit les directives suivantes:

2014/35/EU

Directiva sobre material eléctrico destinado a utilizarse con determinados límites de tensión (Directiva sobre Baja Tensión)
Directive relating to electrical equipment designed for use within certain voltage limits (Low Voltage Directive)
Directive relative aux matériels électriques à employer dans certaines limites de tension (Directive de basse tension)

2014/30/EU

Directiva de Compatibilidad Electromagnética (CEM)
Directive for Electromagnetic Compatibility (EMC)
Directive de Compatibilité Electromagnétique (CEM)

2015/863/EU

Directiva sobre restricción de ciertas sustancias peligrosas en equipos eléctricos y electrónicos (Directiva RoHS)
Restriction on the use of certain hazardous substances in electrical and electronic equipment directive (RoHS directive)
Directive relative à la limitation des substances dangereuses dans les équipements électriques et électroniques (Directive RoHS)

Cumple con las siguientes Normas | Meet the following Standards | Accomplit les Normes suivantes

EN 61010-1:

Requisitos de seguridad de equipos eléctricos de medida, control y uso en laboratorio. Parte 1: Requisitos generales
Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 1: General requirements
Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire -- Partie 1: Exigences générales

EN 61010-2-010:2014

Requisitos de seguridad de equipos eléctricos de medida, control y uso en laboratorio. Parte 2-020: Requisitos particulares para equipos de laboratorio utilizados para el calentamiento de materiales.
Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-010: Exigences particulières pour appareils de laboratoire utilisés pour l'échauffement des matières

EN 61326-1:2013

Material eléctrico para medida, control y uso en laboratorio. Requisitos de compatibilidad electromagnética (CEM). Parte 1: Requisitos generales.

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

Matériel électrique de mesure, de commande et de laboratoire - Exigences relatives à la CEM - Partie 1: Exigences générales

EN 61000-3-2

Compatibilidad electromagnética (CEM) – Parte 3-2: Límites – Límites para las emisiones de corriente armónica

Electromagnetic compatibility (EMC) - Part 3-2: Limits – Limits for harmonic current emissions

Compatibilité électromagnétique (CEM) - Partie 3-2 : Limites - Limites pour les émissions de courant harmonique


EN 61000-3-3

Compatibilidad electromagnética (CEM). Parte 3-3: Límites. Limitación de las variaciones de tensión, fluctuaciones de tensión y flicker en las redes públicas de suministro de baja tensión para equipos con corriente asignada ≤ 16 A por fase y no sujetos a una conexión condicional.

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

Compatibilité électromagnétique (CEM) - Partie 3-3: Limites - Limitation des variations de tension, des fluctuations de tension et du papillotement dans les réseaux publics d'alimentation basse tension, pour les matériels ayant un courant assigné ≤ 16 A par phase et non soumis à un raccordement conditionnel

Beriain, a 17 de Marzo de 2020

 **AUXILAB, S. L.**
N.º F. ESB 31072218
MATERIAL PARA LABORATORIO
Políg. Morea Norte, Calle D N 6 · Tel. 34-948 310513
31191 BERIAIN-NAVARRA (ESPAÑA)

Rubén Martínez
Técnico de Producto /Product Technician

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY
DÉCLARATION DE CONFORMITÉ CE

El fabricante | The manufacturer | **Le fournisseur** : AUXILAB, S.L.

Declara que el equipo | Declare that the equipment | **Declare que l'appareil:**

ESTUFAS | DRYING OVENS | **ÉTUVES**

Código | Code | **Référence:**

JBB001, JBB002, JBB003, JBB004, JBB005
JBD001, JBD002, JBD003, JBD004, JBD005,
JBD006, JBD007, JBD008, JBD009

Serie | Series | **Série:**

631 Plus | 632 Plus | 636 Plus

Cumple con las siguientes directivas | Medt the following directives | **Accomplit les directives suivantes:**

2014/35/EU

Directiva sobre la armonización de las legislaciones de los Estados miembros en materia de comercialización de material eléctrico destinado a utilizarse con determinados límites de tensión Texto pertinente a efectos del EEE

Directive relating to he harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits Text with EEA relevance

Directive relative à l'harmonisation des législations des États membres concernant la mise à disposition sur le marché du matériel électrique destiné à être employé dans certaines limites de tension Texte présentant de l'intérêt pour l'EEE

2014/30/EU

Directiva sobre la armonización de las legislaciones de los Estados miembros en materia de compatibilidad electromagnética (refundición) Texto pertinente a efectos del EEE

Directive relating to the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) Text with EEA relevance

Directive relative à l'harmonisation des législations des États membres concernant la compatibilité électromagnétique (refonte) Texte présentant de l'intérêt pour l'EEE

Cumple con las siguientes Normas | Meet the following Standars | **Accomplit les Normes suivantes :**

EN 61010-1:2011

Requisitos de seguridad de equipos eléctricos de medida, control y uso en laboratorio. Parte 1: Requisitos generales

Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 1: General requirements

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire -- Partie 1: Exigences générales

EN 61326-1:2013

Material eléctrico para medida, control y uso en laboratorio. Requisitos de compatibilidad electromagnética (CEM). Parte 1: Requisitos generales.

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

Matériel électrique de mesure, de commande et de laboratoire - Exigences relatives à la CEM - Partie 1: Exigences générales

EN 61000-3-2: 2014

Compatibilidad electromagnética (CEM). Parte 3-2: Límites. Límites para las emisiones de corriente armónica (equipos con corriente de entrada ≤ 16 A por fase).

Safety requirements for Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)

Règles de sécurité Compatibilité électromagnétique (CEM) - Partie 3-2: Limites - Limites pour les émissions de courant harmonique (courant appelé par les appareils ≤ 16 A par phase)

EN 61000-3-3: 2013

Compatibilidad electromagnética (CEM). Parte 3-3: Límites. Limitación de las variaciones de tensión, fluctuaciones de tensión y flicker en las redes públicas de suministro de baja tensión para equipos con corriente asignada ≤ 16 A por fase y no sujetos a una conexión condicional.

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

Compatibilité électromagnétique (CEM) - Partie 3-3: Limites - Limitation des variations de tension, des fluctuations de tension et du papillotement dans les réseaux publics d'alimentation basse tension, pour les matériels ayant un courant assigné ≤ 16 A par phase et non soumis à un raccordement conditionnel

Beriain, 19 de Junio de 2020

 **AUXILAB, S. L.**
N. I. F. ESB 31072218
MATERIAL PARA LABORATORIO
Políg. Morea Norte, Calle D N6 - Tel. 34-948 310513
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Rubén Martínez,
Técnico de producto