HIMEDIA®
For Life is Precious

HiMedia Laboratories Pvt. Ltd.

Date: 01st January 2021

TO WHOMSOEVER IT MAY CONCERN

We hereby certify that,

Sanmedico SRL
Str. Corobceanu 7A, Apt.9,
MD-2012, CITY CHISINAU
Republic of Moldova,
Tel:-00-373-231 31515 / 00-373-222 60595
Fax:-00-373-22 62 30 32
E-mail: sanmedico.office@gmail.com

have been appointed by us as our **Exclusive Authorized Distributor** for selling our Products in **MOLDOVA**

This certificate is valid upto 31st December 2022.

This Authorization Letter shall stand effective from the date of signing and can be terminated by either party with two months advance notice.

For HIMEDIA LABORATORIES PVT. LTD.,

V.M.WARKE.
DIRECTOR – SALES & MARKETING

HIMEDIA LABORATORIES PVT. LTD. Himedia

Digitally signed by Monastîrschii Viorica
Date: 2022.06.30 11:02:29 EEST
Reason: MoldSign Signature
Location: Moldova

REGISTERED OFFICE - 23, Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel: +91-22-6116 9797 / 2500 1607 | Fax: +91-22-2500 2286
CORPORATE OFFICE - A-516, Swastik Disha Business Park, Via Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel: +91-22-6147 1919 / 2500 3747 | Fax: +91-22-6147 1920 / 2500 5764 | Email: info@himedialabs.com
Web: www.himedialabs.com

Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirement of directives (98/79/EC) In-Vitro Diagnostic Devices Directive.

Certificate No.: CE-12574

Manufacturer

Name : **M/S. HIMEDIA LABORATORIES PVT. LTD.**

Address : **23, VADHANI INDUSTRIAL ESTATE LBS MARG, MUMBAI- 400086, MAHARASHTRA, INDIA**

Products : **HI-GEL™ RUN0610, HI-GEL™ RUN1014, ELECTROPHORESIS POWER SUPPLY(4 TERMINAL), ELECTROPHORESIS POWER SUPPLY (2 TERMINAL), HI-GEL™ RUN0608, HI ECO MINI HORIZONTAL ELECTROPHORESIS SYSTEM, WEE VERT® PROTEIN ELECTROPHORESIS SYSTEM, WEE BLOT™ ELECTROPHORESIS SYSTEM, HI-GEL™ RUN 100 WELL, HI-GEL™ CASTER, CELLULOSE ACETATE ELECTROPHORESIS SYSTEM, PRIMA DUO, PRIMA 96, ECO 96, PRIMA TRIO, PRIMA 96PLUS, PRIMA 384, WEE 16®, WEE 32®, WEE 16 GO®, INSTA Q96®, INSTA Q48®M4, INSTA Q48®M2, INSTA Q96® PLUS, INSTA Q96®-6.0, INSTA NX®, INSTA NX® MAG32, INSTA NX® MAG96, HI-UV MAX, HI-WHITE SET, HI-UV INTENSE, HI-UV DUO, TABSPIN®006, TABSPIN®012, HI-REFRI™24, HIPER® TEMP SHAKER, HIPURA® SANITIZER, WEE DRY™**

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Directive (98/79/EC) In-Vitro Diagnostic Devices Directive.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.co.uk/verify

Date of Certification	16th March 2021
1st Surveillance Audit Due	15th March 2022
2nd Surveillance Audit Due	15th March 2023
Certificate Expiry (subject to the company maintaining its system to the required standard)	15th March 2024

Authorised Signatory

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

Quality Austria
has issued an IQNet recognized certificate that the organization:

HiMedia Laboratories Pvt. Ltd.
Plot NO. C40, ROAD - 21Y, WAGLE INDUSTRIAL ESTATE, THANE (WEST) - 400604 MAHARASHTRA, INDIA

for the following scope:

Design, Development & Testing of Microbiology, Animal Cell Culture, Plant Tissue Culture & Molecular Biology products

EAC: 34

has implemented and maintains a

QUALITY MANAGEMENT SYSTEM

which fulfils the requirements of the following standard

ISO 9001:2015

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Issued on:	2022-02-28
Validity date:	2025-02-27
Quality Austria certified since:	2022-02-28

Registration Number: AT-27302/0

PARTNER OF IQNet

Alex Stoichitoiu
President of IQNet

Mag. Friedrich Khuen-Belasi
Authorised Representative of Quality Austria

qualityaustria
Succeed with Quality

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

Quality Austria
has issued an IQNet recognized certificate that the organization:

HiMedia Laboratories Pvt. Ltd.
Plot NO. C40, ROAD - 21Y, WAGLE INDUSTRIAL ESTATE, THANE (WEST) - 400604 MAHARASHTRA, INDIA

for the following scope:

Design, Development & Testing of Biosciences Products for application in Microbiology, Animal Cell Culture & Molecular Biology products

EAC: 34

has implemented and maintains a

QUALITY MANAGEMENT SYSTEM

which fulfils the requirements of the following standard

ISO 13485:2016

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Issued on:	2022-02-28
Validity date:	2025-02-27
Quality Austria certified since:	2022-02-28

Registration Number: AT-00391/0

PARTNER OF IQNet

Alex Stoichitoiu
President of IQNet

Mag. Friedrich Khuen-Belasi
Authorised Representative of Quality Austria

qualityaustria
Succeed with Quality

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

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Name of the Product : **Bacillus Atrophaeus Spore strip**
Code No. : **LA924**
Section 1 : **Chemical Identification**

Code No.	: LA924
Name of the Product	: Bacillus Atrophaeus Spore strip
Produced by	: HiMedia Laboratories Pvt. Ltd.
Address	: 23, Vadhani Indl. Estate, LBS Marg, Mumbai 400 086, India.
Tel. No.	: 2500 0970, 2500 1607 Fax No. 022 2500 2468

Section 2 : **Bacillus Atrophaeus Spore strip**

Section 3 : **Hazards Identification**
Hazard : Not classified as hazardous. This product contains no hazardous constituents or the concentration of all chemicals constituents are below the regulatory threshold limits.

Section 4 : **First - Aid Measures**
No specific measures necessary.

Section 5 : **Fire Fighting Measures**
Not combustible.

Section 6 : **Accidental Release Measures**
No specific measures necessary.

Section 7 : **Handling and Storage**
Handling - Refer to Section 8
Storage - Store below 30°C

Section 8 : **Exposure Controls / Personal Protection**
Wear appropriate NIOSH/MSHA-approved respirator, safety goggles, other protective clothing.

Section 9 : **Physical and Chemical Properties**
Appearance: Filter paper strip impregnated with spores of Bacillus atrophaeus ATCC 9372 (Formerly B.subtilis). For ETO and Dry heat sterilization

Section 10 : **Stability and Reactivity**
Stability : Product is stable if stored as per the conditions specified under storage of Section No. 7.

Section 11 : **Toxicological Information**
Non toxic.

Section 12 : **Ecological Information**
Data not available

Section 13 : **Disposal Considerations**
No special disposal method required except that it be in accordance with current and local authority regulation. Autoclave all possible indicators before eliminating them

Section 14 : **Transport Information**
UN No. : Not applicable.

Section 15 : **Regulatory Information**
Risk Phrases : Not applicable
Safety Phrases : Not applicable

Section 16 : **Other Information**
The information contained in this data sheet represents the best information currently available to us. However, no warranty is made with respect to its completeness and we assume no liability resulting from its use. The information is offered solely for user's obligation to investigate and determine the suitability of the information for their particular purpose.

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Name of the Product : **Geobacillus Stearothermophilus Ampoule**
Code No. : **LA926**

Section 1 : **Chemical Identification**

Code No.	: LA926
Name of the Product	: Geobacillus Stearothermophilus Ampoule
Produced by	: HiMedia Laboratories Pvt. Ltd.
Address	: 23, Vadhani Indl. Estate, LBS Marg, Mumbai 400 086, India.
Tel. No.	: 2500 0970, 2500 1607 Fax No. 022 2500 2468

Section 2 : **Geobacillus Stearothermophilus Ampoule**

Section 3 : **Hazards Identification**
Hazard : Not classified as hazardous. This product contains no hazardous constituents or the concentration of all chemicals constituents are below the regulatory threshold limits.

Section 4 : **First - Aid Measures**
No specific measures necessary.

Section 5 : **Fire Fighting Measures**
Not combustible.

Section 6 : **Accidental Release Measures**
No specific measures necessary.

Section 7 : **Handling and Storage**

Handling	- Refer to Section 8
Storage	- Store below 30°C

Section 8 : **Exposure Controls / Personal Protection**
Wear appropriate NIOSH/MSHA-approved respirator, safety goggles, other protective clothing.

Section 9 : **Physical and Chemical Properties**
Appearance: Spore ampoule is a self contained Biological indicator used for validating steam sterilization at 121°C. It is made of an external plastic tube with a perforated cap. It contains inside inoculated spores of Geobacillus stearothermophilus ATCC 7953 in a filter paper strip and an ampoule having adequate culture medium with a pH indicator.

Section 10 : **Stability and Reactivity**
Stability : Product is stable if stored as per the conditions specified under storage of Section No. 7.

Section 11 : **Toxicological Information**
Non toxic.

Section 12 : **Ecological Information**
Data not available

Section 13 : **Disposal Considerations**

No special disposal method required except that it be in accordance with current and local authority regulation. Autoclave all possible indicators before eliminating them

Section 14 : **Transport Information**

UN No. : Not applicable.

Section 15 : **Regulatory Information**

Risk Phrases : Not applicable

Safety Phrases : Not applicable

Section 16 : **Other Information**

The information contained in this data sheet represents the best information currently available to us. However, no warranty is made with respect to its completeness and we assume no liability resulting from its use. The information is offered solely for user's obligation to investigate and determine the suitability of the information for their particular purpose.

■

Bowie and Dick Test Pack **LA1029**

Description :

Bowie and Dick test pack consists of a series of steam penetration (air removal) barriers in the center of which is a chemical indicator sheet. During processing, the cycle must remove or displace the air from within the barrier material, and replace it with steam through the pack. A color change from Pink to Brown/ Black indicates adequate steam penetration.

Application :

Using the single use Bowie and Dick test pack allows for performance of steam penetration testing in an effective and simple way on a daily basis. The test pack should be placed into an empty autoclave chamber and processed using the recommended autoclave program. A vacuum cycle of 134°C for 3.5 minutes or 121°C for 15 minutes is recommended as per the ANSI/ AAMI/ ISO 11140 standards. The Bowie and Dick test pack verifies that the pre-vacuum autoclave effectively removes air. The test itself provides repeatable, reliable, accurate results and is non-reversible making documentation of the verification safe and easy

Features and Benefits :

1. Conforms to EN867-4 (The European standard for alternative BD Tests) and ANSI/AAMI/ ISO 11140-3 and 11140-1
2. Manufactured in an ISO 13485 compliant facility
3. Test pack is non-toxic and indicator is free of lead and other heavy metals
4. Distinct non-reversible color change from Pink to Brown/ Black
5. Barrier material made from 99% recycled paper
6. Robust, easy to handle construction
7. Does not retain heat
8. No preferential route of steam entry, can be placed either way in autoclave
9. Single use/ disposable
10. Non-hazardous products according to OSHA

Bowie and Dick Test Pack **LA1029**

Directions for Use (as printed on each pack) :

1. Warm up sterilizer/ autoclave with an empty chamber run
2. Put Bowie and Dick single test pack horizontally in the sterilizer/ autoclave
3. Start the test run (recommended 134°C for 3.5 minutes or conversely 121°C for 15 minutes)
4. After test run is completed, remove the test pack immediately from the chamber
5. Open the test pack, take out the test sheet, examine and document result
6. Compare the indicator's colour shade at the edge of the test sheet with the indicator color in the middle of the test sheet. If the sterilization cycle is effective, the indicator color changes completely from pink to brown/ black. If the sterilization cycle is not effective, the color change will be incomplete. In this case, check the sterilizer/ autoclave.

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Email : info@himedialabs.com | Web : www.himedialabs.com