

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 |

Daniel..



Authorised Signatory

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851

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





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

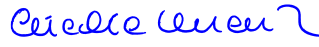
This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

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

Registration Number: AT-27302/0




Alex Stoichitoiu
President of IQNet


Mag. Friedrich Khuen-Belasi
Authorised Representative
of Quality Austria



IQNet Partners*:

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CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
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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



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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

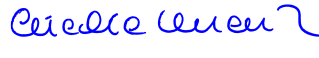
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| Issued on: | 2022-02-28 |
| Validity date: | 2025-02-27 |
| Quality Austria certified since: | 2022-02-28 |

Registration Number: AT-00391/0




Alex Stoichitoiu
President of IQNet


Mag. Friedrich Khuen-Belasi
Authorised Representative
of Quality Austria



IQNet Partners*:

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Metaloops

**LA012, LA730, LA014, LA019
LA020, LA021, LA022,
LA023, LA039, LA040 &
LA051.**

An inoculation loop, simple tool used for streaking. The loop of wire at the tip is made of nichrome and handle with stainless steel.

Application : Microbiology laboratory, Molecular biology laboratory, Culture preparation and various other laboratories.

| Product Name | Product Code | Description | Dia (mm) | Packing (Nos) |
|---------------------------------|--------------|---|--|-----------------------|
| Metaloop Ch-2 | LA012 | Changeable nichrome loop embedded in Brass rod with heat resistant handle. | 2.00 | 1X 8 1X24 |
| Metaloop Ch-3 | LA730 | Changeable nichrome loop embedded in Brass rod with heat resistant handle. | 3.00 | 1X 8 1X24 |
| Metaloop-SS-4 | LA014 | Fixed nichrome loop embedded in SS rod with heat resistant handle. Calibrated to 0.01 ml. | 4.00 | 1X 8 1X24 |
| Nichrome Loop-D-4 | LA019 | Double wound nichrome loop. Calibrated to 0.01 ml. | 4.00 | 5X5 5X10 10X10 |
| Nichrome Loop-D-2 | LA020 | Double wound nichrome loop. Calibrated to 0.005 ml. | 2.00 | 5X5 5X10 10X10 |
| Nichrome Loop-D-1 | LA021 | Double wound nichrome loop. Calibrated to 1µl. | 1.30 | 5X5 5X10 10X10 |
| Straight Wire (Nichrome) | LA022 | Suitable for stab inoculation. | - | 5X5 5X10 10X10 |
| Assorted Nichrome Loops | LA023 | Each packet contains 3 pieces of each Nichrome loop. Straight and Double wound Wire. | 4.00(0.01ml), 2.00(0.005ml) & 1.30 (1µl) | 2X10 5X10 10X10 |
| Metal Loops Holder Ch-4 | LA039 | Changeable nichrome loop with nichrome wire in Brass rod with heat resistant handle. | 4.00 | 1X8 1X24 |

| | | | | |
|---------------------------|--------------|---|------|----------------------|
| Metal Loops Holder | LA040 | (w/o loop) Brass rod holder with heat resistant handle where any size of nichrome wire can be inserted. | - | 1X8 1X24 |
| Nichrome Loop -D-3 | LA051 | Double wound. Calibrated to 0.006ml. | 3.00 | 5X5 5X10 10X10 |

Product Feature:

- Heat Resistant handle.

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.