

Anexa tehnica, Lot 1

Sistem de producere a apei ultrapuremodel Labaqua Bio, Biosan, Letonia

Parametri solicitati	Parametri oferiti
Domeniul de utilizare Laborator de genetică moleculară Parametru Specificația Tipul sistemului Amplasat pe masă Tip apă generată Ultrapură grad I Rezistivitate apa de grad I Maxim 0.055 $\mu\text{S}/\text{cm}$ la 25 °C Nivel carbon organic total Maxim 2 ppb R-naza Maxim 0.004 ng/ml D-naza Maxim 0.024 pg/ μl Bacterii Maxim 0.005 CFU/ml Endotoxine Maxim 0.001 EU/ml Particule Mai mari de 0.22 μm maxim 1 per ml Debitul nominal de apă ultrapură Minim 2 l/min Presiunea apei de alimentare 1 – 6 bar Conductivitatea apei de alimentare minim 999 $\mu\text{S}/\text{cm}$ Senzor de conductivitate Da Container Minim 10 l cu dispenser Sursă de alimentare Tensiune de alimentare 220V, 50 Hz Tip fir de alimentare Shuko Consumabile Filtre Filtre suficiente pentru minim 2 m ³ de apă ultrapură și 2 ani de utilizare Training Training pentru utilizator Da, prezentare generală, pregătirea de lucru, operarea dispozitivului, mentenanța zilnică Training pentru ingineri Da, Testarea performanței, mentenanța periodică Documente Manual de utilizare Română Manual de deservire Română sau Engleză Logistică Transportare la locul solicitat Da Instalare și darea în exploatare Da Testare Da Garanție Perioadă Minim 2 ani Efectuarea mentenanței periodice în garanție: De către furnizor, conform manualului de deservire tehnică.	Domeniul de utilizare Laborator de genetică moleculară Parametru Specificația Tipul sistemului Amplasat pe masă Tip apă generată Ultrapură grad I Rezistivitate apa de grad I 0.055 $\mu\text{S}/\text{cm}$ la 25 °C Nivel carbon organic total < 5 ppb R-naza Maxim 0.01 ng/ml D-naza Maxim 4 pg/ μl Bacterii Maxim 0.01 CFU/ml Endotoxine Maxim 0.001 EU/ml Particule Mai mari de 0.22 μm 1 per ml Debitul nominal de apă ultrapură 2 l/min Presiunea apei de alimentare 0.5 – 5 bar Conductivitatea apei de alimentare 1300 $\mu\text{S}/\text{cm}$ Senzor de conductivitate Da Container 30 l cu dispenser Sursă de alimentare Tensiune de alimentare 220V, 50 Hz Tip fir de alimentare Shuko Consumabile Filtre Filtre suficiente pentru 2 m ³ de apă ultrapură și 2 ani de utilizare Training Training pentru utilizator Da, prezentare generală, pregătirea de lucru, operarea dispozitivului, mentenanța zilnică Training pentru ingineri Da, Testarea performanței, mentenanța periodică Documente Manual de utilizare Română Manual de deservire Română sau Engleză Logistică Transportare la locul solicitat Da Instalare și darea în exploatare Da Testare Da Garanție Perioadă 2 ani Efectuarea mentenanței periodice în garanție: De către furnizor, conform manualului de deservire tehnică.

Labagua Bio, ultrapure water system

DESCRIPTION

Labagua ultrapure systems are multi-purpose water purification systems. The Labagua systems produce ultrapure and pure water directly from tap water.

Labagua Bio system produces water with very low organic and RNase/DNase content that is intended for the use in molecular biology, including RNase sensitive applications.

Any configuration of a Labagua ultrapure system produces both ultrapure and pure water. Ultrapure (Grade 1) water is dispensed through the point-of-use filter on the front panel. Pure (Grade 2) water is dispensed directly from the storage tank.

Labagua ultrapure water can be used for the most demanding applications including, but not limited to: **Inorganic trace analysis, Liquid chromatography, Cell culture, Molecular biology.**

With resistivity of 18.2 Mega — Ohm*cm (0.055 µS/cm) ultrapure water produced by a Labagua system exceeds requirements of all relevant standards (ISO 3696 Grade 1, ASTM Type I, CLSI Type I). Purified water is collected in a storage tank. An integrated recirculation system ensures consistent quality of water and reduces total organic carbon (TOC) to very low levels: <5ppb.

Pure water produced by the Labagua systems complies with the requirements of ISO 3696 Grade 2 water and can be used for labware washing, wet chemistry methods, flame spectrophotometers, etc.

All Labagua systems have a controller with a color graphic LCD display for water quality indication. The LCD display provides all necessary information about system status, as well as system flow-chart the remaining pre-filter life and deionization (DI) module performance. The smart DI module monitoring system also provides a reduction in running costs. A user is instructed to replace the DI module only when the module is near the end of its service life.

All cartridges and filters are easily accessible and no tools are required to replace them. The Labagua system can be installed on a laboratory bench or mounted on a wall.

Features:

- **Volumetric dispense** - enables the user to set accurate dispensing volume for each dispense cycle. The dispense volume can be set either from the keyboard or by using "teaching" mode.
- **Water quality** - embedded recirculation loop ensures stable premium water quality and enables practical elimination of Total Organic Carbon (TOC).
- **Low running costs** - performance of the deionization and polishing modules is constantly monitored. Monitoring algorithm enables cutting running costs, as replacement of the modules is requested only when service life is close to the end.
- **Total organic carbon (TOC) monitor** - organic contaminants may not have effect on conductivity of water, so conductivity sensors cannot be used for TOC monitoring. Therefore, a special TOC monitoring module is needed to measure TOC level.
- **Color graphic LCD display** - system component status is reflected on the display in an intuitive color pattern (Green/Yellow/Red).
- **System flowchart** - shows all component status and water quality parameters at a glance.

The Labagua systems include:

- Boost pump
- Pre-filter set
- Reverse osmosis module
- Deionization module
- Final stage polishing module
- 30L storage tank with an integrated Grade 2 dispensing valve
- Recirculation system



CAT. NUMBER

	30l storage tank
BS-070106-A02	230VAC 50Hz Euro plug
BS-070106-A06	230VAC 50/60Hz UK plug
BS-070106-A03	230VAC 50/60Hz AU plug
	60l storage tank
BS-070107-A01	230VAC 50/60Hz Euro plug
BS-070107-A06	230VAC 50/60Hz UK plug
BS-070104-HK	IQ/OQ/PQ/DQ documentation for LabAqua

Model specific modules:

- **Labqua Trace** - Point-of-use microfilter
- **Labqua HPLC** - Point-of-use microfilter, TOC monitor
- **Labqua Bio** - Point-of-use ultrafilter, UV sterilization module, TOC monitor

Compliance of the system with the technical specification is ensured if the following minimum tap water requirements are followed and the maintenance requirements specified in the user manual are carried out in a timely manner.

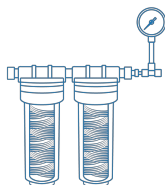
- Type of feedwater: Potable
- Minimum pressure: ≥ 0.5 bar
- Maximum pressure: ≤ 5 bar
- Conductivity: $<1300 \mu\text{S/cm}$
- Temperature: 5 to 35°C
- pH: 4 - 10
- Fouling Index: <10
- Iron: <0.1 ppm as CaCO_3
- Aluminum: <0.05 ppm as CaCO_3
- Manganese: <0.05 ppm as CaCO_3
- Free Chlorine: <1 ppm
- Langerier Saturation Index: $<+0.2$
- TOC: <2000 ppb

SPECIFICATIONS

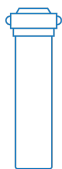
Ultrapure (Grade 1) water resistivity	18.2 MΩ x cm
Ultrapure (Grade 1) water conductivity	0.055 $\mu\text{S/cm}$
Pure (Grade 2) water resistivity	10 MΩ x cm
Pure (Grade 2) water conductivity	0.1 $\mu\text{S/cm}$
TOC	< 5 ppb
RNase	< 0.01 ng/ml
DNase	< 4 pg/ μl
Bacteria	< 0.01 CFU/ml
Endotoxins	< 0.001 EU/ml
Particles $> 0.22 \mu\text{m}$	$< 1/\text{ml}$
Deionization module life (standard module)	1 m ³
Storage tank	30 l
Feed water pressure	0.5 – 5 bar
Feed water conductivity	$< 1300 \mu\text{S/cm}$
Dimensions (W×D×H)	320×560×620 mm
Weight	26 kg
Power consumption	130 W
Nominal operating voltage	100-240VAC 50/60Hz



External pre-filter set
(polyphosphate/carbon/1 µm)
with manometer
BS-070104-LK



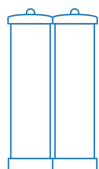
External pre-filter set
(carbon/1 µm) with manometer
BS-070104-KK



Internal prefilter set
BS-070104-AK



Polishing module
BS-070104-BK



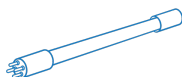
Deionization module
BS-070104-IK



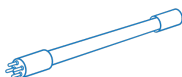
Microfilter - 0.22µm sterile
BS-070104-FK



Ultrafilter
BS-070104-GK



UV bulb 254 nm
BS-070104-RK



UV bulb 185 nm
BS-070104-DK



Storage tank 60l
BS-070102-SK

Storage tank with base, tap and
multipoint level switch, 60 l



Storage tank 100l
BS-070102-FK

Storage tank with base, tap and
multipoint level switch, 100 l



Remote grade 1 water dispenser
BS-070110-AK

Ultrapure water dispenser is
designed to dispense ultrapure
water that complies with ISO
3696 Grade I water
requirements.



Remote grade 2 water dispenser
BS-070104-JK

Universal remote dispenser set
with 3 m supply hose and water
distribution module

EU Declaration of Conformity

Unit type Water purification systems

Models Labaqua Trace, Labaqua HPLC, Labaqua Bio

Serial number 14 digits styled XXXXXYYMMZZZZ, where XXXXXX is model code, YY and MM – year and month of production, ZZZZ – unit number.

Manufacturer SIA BIOSAN
Latvia, LV-1067, Riga, Ratsupites str. 7/2

The objects of the declaration described above is in conformity with the following relevant Union harmonization legislations:

LVD 2014/35/EU	LVS EN 61010-1:2011 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.
EMC 2014/30/EU	LVS EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.
RoHS3 2015/863/EU	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
WEEE 2012/19/EU	Directive on waste electrical and electronic equipment.

I declare that the Declaration of Conformity is issued under sole responsibility of the manufacturer and belongs to the above-mentioned objects of the declaration.

Svetlana Bankovska
Managing director



Signature

07.02.2020.
Date



BUREAU
VERITAS

Bureau Veritas Certification



EN ISO/IEC 17021-1
S2-424

Certification
Awarded to
Biosan SIA

Rātsupītes iela 7 k-2, Rīga, LV-1067, LATVIA

Brīvības gatve 323, Rīga, LV-1006, LATVIA

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standard detailed below

Standard

ISO 9001:2015

SCOPE OF CERTIFICATION

DEVELOPMENT, PRODUCTION, SALES AND SERVICE OF LABORATORY EQUIPMENT.

Original Cycle Start Date:	25-05-2004
Expiry date of previous cycle:	25-05-2025
Certification / Recertification Audit date:	13-05-2025
Certification/Recertification Cycle Start Date:	26-05-2025
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	25-05-2028

Certificate No.: LV009252

Version: 1

Issue date: 21-05-2025

Certification body address: Bureau Veritas Latvia SIA, Dunties street 17a, Riga, LV-1005, Latvia
Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please call +371 67323246





BUREAU
VERITAS

Bureau Veritas Certification



EN ISO/IEC 17021-1
S2-424

Certification . Awarded to **Biosan SIA**

Rātsupītes iela 7 k-2, Rīga, LV-1067, LATVIA

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Standard

ISO 13485:2016

SCOPE OF CERTIFICATION

DEVELOPMENT, DESIGN, PRODUCTION, SERVICE AND DISTRIBUTION OF MEDICAL DEVICES: DEVICE FOR MEASURING OPTICAL DENSITY (OD), AUTOMATIC MICROPLATE WASHER, MICROPLATE PHOTOMETER. SALES, STORAGE AND DISTRIBUTION OF ACTIVE AND NON ACTIVE NONIMPLANTABLE MEDICAL DEVICES.

Original Cycle Start Date:	26-05-2022
Expiry date of previous cycle:	25-05-2025
Certification / Recertification Audit date:	13-05-2025
Certification/Recertification Cycle Start Date:	26-05-2025
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	25-05-2028

Certificate No.: LV009253

Version: 1

Issue date: 21-05-2025



Certification body address: Bureau Veritas Latvia SIA, Dunties street 17a, Riga, LV-1005, Latvia
Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please call +371 67323246