

Bureau Veritas Certification



Certification Awarded to

Biosan SIA

Rātsupītes iela 7 k-2, Rīga, LV-1067, 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 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:	NA
Certification / Recertification Audit date:	18-05-2022
Certification/Recertification Cycle Start Date:	26-05-2022
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	25-05-2025



Certificate No.: LV007756

Version: 2

Issue date: 03-07-2023

Certification body address: Bureau Veritas Latvia SIA, Duntes 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 1/1

EU Declaration of Conformity

Unit type	Thermo-Shakers
Models	TS-100, TS-100C, TS-100C Smart, TS-DW, PST-60HL, PST-60HL-4, PST-100HL
Serial number	14 digits styled XXXXXXYYMMZZZZ, 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. LVS EN 61010-2-010:2015 Particular requirements for laboratory equipment for the heating of materials. LVS EN 61010-2-051:2015 Particular requirements for laboratory equipment for mixing and stirring.
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 Date

EXPANDED RANGE OF THERMOBLOCKS FOR THE BEST $m{*}$ THERMO-SHAKERS IN THE WORLD

* Probably



TS-100, TS-100C and TS-100C Smart — robust and reliable everyday device in your laboratory. Versatile range of available blocks, precise and accurate temperature control from +4°C up to +100°C and powerful shaking speed on 2 mm orbit reaching 1400 rpm/min can now meet the most challenging demands.





Medical-Biological **Research & Technologies**

www.biosan.lv



Applications



Clinical sample preparation — Ideal for blood, plasma and serum sample mixing in diagnostic labs, ensuring uniformity for accurate testing results.)



Molecular biology protocols — Facilitates consistent reagent mixing for DNA/RNA extraction, PCR, and enzyme reactions, essential for genetic and biochemical studies.



Cell and tissue culture processing — Supports the preparation of bacterial, yeast, or mammalian cell suspensions, crucial for microbiology and cell biology labs.



Pharmaceutical and drug development research - Enables precise temperature-controlled mixing of reagents and compounds for drug formulation, testing, and stability studies.





O°



Key features



Compact design with low noise operation:

Space-saving and quiet, these devices fit seamlessly into any lab environment.



Variable speed and temperature control:

Adjustable speeds ranging from 250 to 1,400 rpm and heating capabilities from +4 °C to +100 °C (model-dependent) for precise sample processing.



Safety and durability: Built with overheat protection, automatic shutoff features, and robust construction for long-term use in demanding labs.



Advanced digital control and programmability: Easy-to-use interfaces with real-time display and programmable settings.

Ratsupites iela 7 k-2, Riga, Latvia



TS-100C, Thermo-Shaker with cooling for microtubes and PCR plates



ninsan

DESCRIPTION

Thermo–Shaker **TS-100C** provides intensive mixing and temperature control of samples in microtest tubes or PCR plate. This model of Thermo–Shaker differs from TS-100 with a possibility of cooling samples down to +4°C. Features of **TS-100C** meet the highest expectations of users according to many parameters:

- Fast reaching of specified mixing speed and maintenance of equal amplitude of rotation throughout the Thermo–Shaker block;
- 2. Stability of maintaining the preset temperature in a wide range throughout the Thermo–Shaker's block surface;
- 3. LCD display indicates preset and current values of temperature, speed and time of operation;
- 4. Quiet motor operation, compact size, prolonged service life.

Functions of heating and mixing can be performed both simultaneously and independently.

There are five heating and cooling blocks available, including a block with a plastic lid for the PCR-plates. All blocks are mutually interchangeable and can be easily installed on Thermo–Shaker.

The instrument is applicable in:

- Genetic analysis in extraction of DNA, RNA and further sample preparation;
- Biochemical study of enzymatic reactions and processes;
- Extraction of metabolites from cellular material.

Temperature Calibration Function

With the help of the temperature calibration function the user can calibrate the unit approx. $\pm 6\%$ of the selected temperature to compensate differences in the thermal behaviour of tubes from different manufacturers.



CAT. NUMBER

Without thermoblock	Without thermoblock
BS-010143-AAI	230VAC 50/60Hz Euro plug
BS-010143-AAQ	230VAC 50/60Hz UK plug
BS-010143-AA4	230VAC 50/60Hz AU plug
BS-010143-AAJ	100VAC 50/60Hz US plug, 120VAC 60Hz US plug
BS-010143-HK	IQ OQ document
BS-010143-IK	PQ document

SPECIFICATIONS

Temperature setting range	+4°C +100°C
Temperature control range	15°C below ambient +100°C
Temperature setting resolution	0.1°C
Temperature stability	±0.1°C
Temperature accuracy at +37°C	±0.5°C
Average heating speed from +25°C to +100°C	5°C/min
Average cooling speed from +100°C to +25°C	5°C/min
Average cooling speed from +25°C to +4°C	1.8°C/min
Temperature uniformity over the block at +4°C	±0.6°C
Temperature uniformity over the block at +37°C	±0.1°C
Temperature uniformity over the block at +100°C	±0.3°C
Temperature calibration coefficient range	0.9361.063 (± 0.063)
Speed control range	250–1400 rpm
Digital time setting	1 min–96 hrs / non–stop (increment 1 min)
Timer sound signal	+
Orbit	2 mm
Display	LCD, 16 x 2 signs
Microprocessor controlled temperature, mixing speed and operation time	+
Maximum continuous operation time	168 h
Overall dimensions (W×D×H)	220x240x90 mm
Weight	3.7 kg
Input current/power consumption	12 V, 4.9 A / 60 W
External power supply	Input AC 100–240 V; 50/60 Hz; Output DC 12 V





SC-18C BS-010143-AK block

20 × 0.5 ml + 12 × 1.5 ml microtubes



SC-18/02C BS-010143-CK block

20 × 0.2 ml microtubes + 12 × 1.5 ml microtubes



SC-24NC BS-010143-GK block

24 x 1.5 ml microtubes



SC-24C BS-010143-EK block

24 × 2 ml microtubes



SC-96AC BS-010143-FK block

96-well unskirted or semiskirted microplate (0.2 ml) for PCR or 12 × 8 - 0.2ml strips or 96 tubes of 0.2 ml.



VP-8/5C BS-010176-SK block



VP-CL-24C

BS-010176-KK

block



VP-4C BS-010176-GK block

4 × 50 ml conical tubes



VP-CS-24C BS-010176-LK block

24 × 3.6–4.5 ml cryotubes 24 × 1–1.8 ml cryotubes



BS-010176-HK block

8 × 15 ml conical tubes



VP-32C BS-010176-JK block

32 × 0.5 ml microtubes



VP-CV-20C BS-010176-IK block

20 × 10mm cuvettes



VP-20C BS-010176-TK

20 × ø12 mm round bottom tubes

block