

## EC Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

This is to certify that following IVD products:

**IW8 Intellispeed Washer**

Cat. Nr. BS-060106-IVD1  
BS-060106-IVD2  
BS-060106-IVD3

**3D-IW8 Inteliwasher**

Cat.Nr. BS-060102-IVD1  
BS-060102-IVD2  
BS-060102-IVD3

and their associated components listed in the attached Device Schedule,

**Classified as:** "all other IVD Medical Devices" according to IVD Directive as modified by 2007/47/EC, Annex I rules,

**Manufactured by:** SIA Biosan, Ratsupites str. 7, build.2, Riga, Latvia, Post code LV-1067

1. Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
2. Undersigned declares to fulfil the obligations imposed by Annex III section 2 to 5:
  - a. Availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
  - b. The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
  - c. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).
3. SIA Biosan declares using Quality System in place based on ISO 13485:2015
4. This Declaration of Conformity is signed below, certifying that the requirements of Annex I and Annex III have been met and documented.

SIA BIOSAN  
Managing Director

/S. Bankovska /

Date of Issue: 13/09/2018  
Place: Riga, Latvia



SIA BIOSAN  
Developer

/S. Djačenko)

**SIA "Biosan"**

**Postal/Delivery address:**

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**Bank details:**

AS "Swedbank"  
Balasta dambis 15, Riga,  
LV-1047, Latvia  
SWIFT: HABALV22  
LV97HABA0551013587195

DEVICE SCHEDULE

IW8 Intelispeed and 3D-IW8 Inteliwasher systems includes following components, accessories and consumables:

Component	Catalog number
3D-IW8 incl. washing solution and waste bottles & external power supply unit	BS-060102-IVD1
	BS-060102-IVD2
	BS-060102-IVD3
4CHW Logger - 4-channel washing solution weight logger	BS-060102-AK
IW-8 incl. washing solution and waste bottles & external power supply unit	BS-060106-IVD1
	BS-060106-IVD2
	BS-060106-IVD3
4CHW Logger - 4-channel washing solution weight logger	BS-060102-AK
... End of schedule ....	

**SIA "Biosan"**  
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BS-060106-IVD2  
BS-060106-IVD3

**3D-IW8 Inteliwasher**

Cat.Nr. BS-060102-IVD1  
BS-060102-IVD2  
BS-060102-IVD3

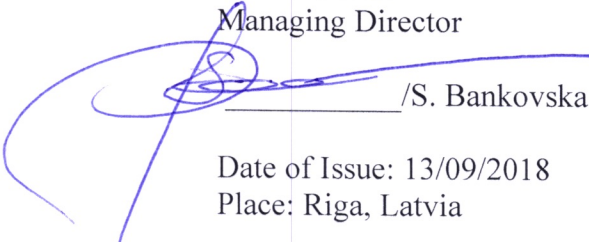
and their associated components listed in the attached Device Schedule,

**Classified as:** "all other IVD Medical Devices" according to IVD Directive as modified by 2007/47/EC, Annex I rules,

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Managing Director

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Medical-Biological  
Research & Technologies

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Component	Catalog number
3D-IW8 incl. washing solution and waste bottles & external power supply unit	BS-060102-IVD1
	BS-060102-IVD2
	BS-060102-IVD3
4CHW Logger - 4-channel washing solution weight logger	BS-060102-AK
IW-8 incl. washing solution and waste bottles & external power supply unit	BS-060106-IVD1
	BS-060106-IVD2
	BS-060106-IVD3
4CHW Logger - 4-channel washing solution weight logger	BS-060102-AK
... End of schedule ...	

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# IW-8, Intelispeed washer

## DESCRIPTION

Intelispeed Washer **IW-8** is designed for washing of standard flat-bottom 96 well plates and microstrips. The unit is fully programmable ensuring multi-step solution ripening, aspiration (aspiration, combination of aspiration/liquid dispensing and soaking, as well as soaking cycle during a particular period of time).

The unit has 100 user-defined programs. Standard version is supplied with 8-channel washing head for dispensing/aspiration, 3 bottles for washing and rinsing solutions, a waste bottle and bottle with filter. Optional 4-channel washing solution weight logger, **4 CHW Logger** is available.

The unit is designed for washing standard 96-well plates during analyses.

The unit provides:

- Washing mode
- Rinsing mode
- Mixing mode
- Double aspiration
- Possibility of additional solution mixing during time gap between two work cycles
- Possibility to use microtest plates by different manufacturers, ensured by automated plate set up (adjusting to different depths of plate wells)
- Plate and strip washing mode
- User-defined programs with adjustable parameters
- Saving work programs

The unit is designed for use in closed laboratory rooms at temperatures from +10°C to +35°C and relative humidity up to 80% at +25°C decreasing linearly to 50% relative humidity at 35°C.

4-channel washing solution weight logger, **4 CHW Logger** provides automatic control of rinsing solution and waste volumes. The washer shows remaining volume for each bottle as percentage and gives a warning message in case of low solution volume or full waste bottle when **4 CHW Logger** is connected.

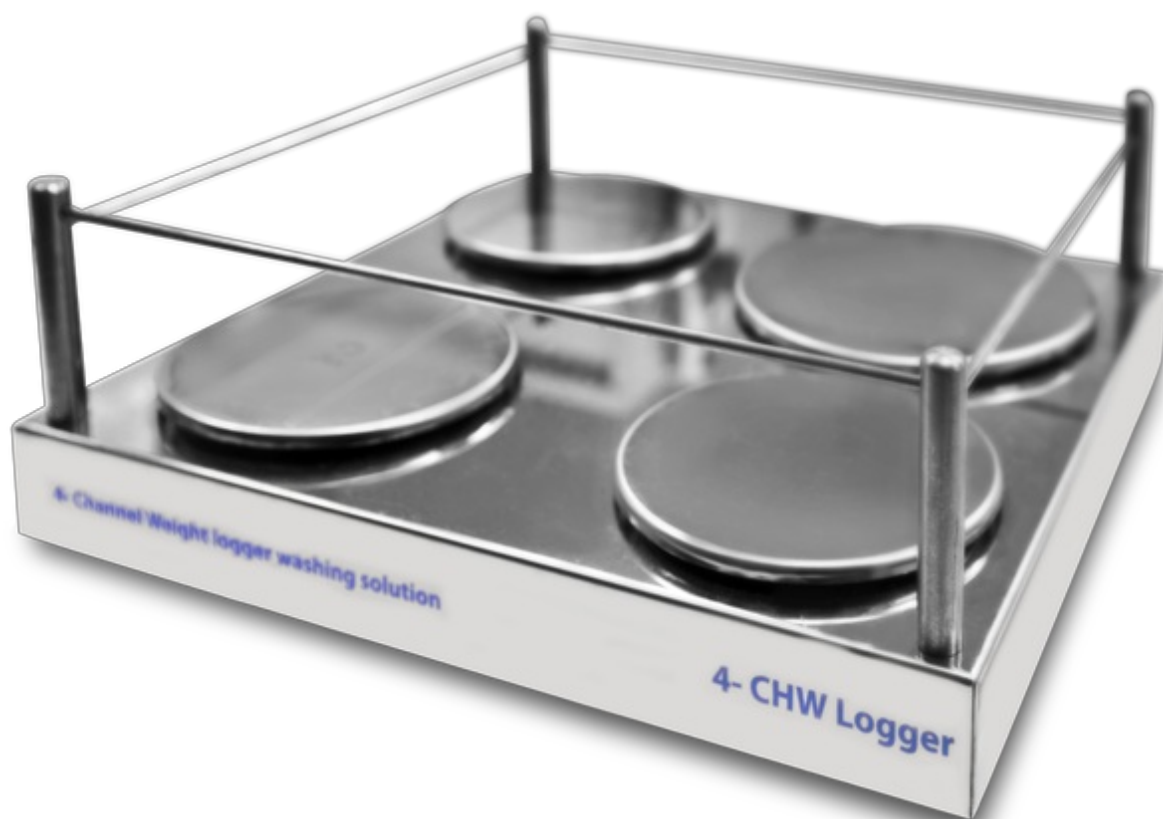


## CAT. NUMBER

BS-060106-AAI	230VAC 50/60Hz Euro plug
BS-060106-AAB	230VAC 50/60Hz UK plug
BS-060106-AA4	230VAC 50/60Hz AU plug
BS-060106-AAJ	100VAC 50/60Hz US plug, 120VAC 60Hz US plug
Russian language interface	Russian language interface
BS-060106-A02	230VAC 50/60Hz Euro plug
BS-060106-AK	IQ OQ document
BS-060106-BK	PQ document

## SPECIFICATIONS

Minimum dispense volume	25 µl
Maximum dispense volume	1600 µl
Dispense increment	25 µl
Dispensing accuracy	±2.5%
Allowed residual liquid volume in plate well	not more than 2 µl
Number of wells washed simultaneously	8
Aspiration time	0.2–3 s
Number of washing cycles for each channel	1–15
Aspiration/dispensing speed	3 levels
Max. number of channels in a program	2
Choice of 3 washing liquid bottles	+
Soaking time	0–300 s (increment 10 s)
Shaking time	0–150 s (increment 5 s)
Number of washed rows	1 – 12
Time of plate single wash (350 µl), not more	45 s
Number of programs	101
Plate platform and washing head movement	automated
Indication of operation modes	8-line LCD
Overall dimensions (W×D×H)	375 × 345 × 180 mm
Weight	9.6 kg
Input current/power consumption	12 V DC, 1.8 A / 22 W
External power supply	Input AC 100–240 V; 50/60 Hz; Output DC 12 V



4 CHW Logger  
BS-060102-AK

4-channel washing solution weight logger, **4 CHW Logger** provides automatic control of rinsing solution and waste volumes. The washer shows remaining volume for each bottle as percentage and gives a ...

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