

## 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"**

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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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