

DECLARATION OF CONFORMITY



The designated device complies with the relevant fundamental requirements of the directives and standards listed below. In the case of unauthorized modification to the device, this declaration becomes invalid.

DESIGNATION MAS-100 ISO NT
APPLICATION MICROBIOLOGICAL AIR SAMPLER

RELEVANT DIRECTIVES

2014/35/EC	European Union	Low voltage directive
2014/30/EC	European Union	Electromagnetic compatibility
2011/65/EC	European Union	RoHS + 2015/863/EU
2012/19/EC	European Union	WEEE
REG (EC) 1907/2006	European Union	REACH
SJ/T11363-2006	P.R. of China	RoHS
TP TC 004&020/2011	Custom Union	EAC

APPLIED STANDARDS

EN 61010-1: 2020-3	IEC 61000-3-2:2014
IEC 61326-1: 2020-10	IEC 61000-3-3:2013
EN 55011: 2016, class B	EN 61000-3-2:2014
CISPR 11: 2015; class B	EN 61000-3-3:2013
	EN 60529: 1991 + A1:2 (only with optional IP54 accessory)

GAMP

Developed and validated according to GAMP 5.
Usage as category 3 recommended (off-the-shelf product).

MANUFACTURER

Company	MBV AG	Signatory	Beat Glauser
Address	Industriestrasse 9 CH-8712 Stäfa Switzerland	Function	CTO
		Date	13.01.2023
		Signature	

DECLARATION OF CONFORMITY



The designated device complies with the relevant fundamental requirements of the legislation and standards listed below. In the case of unauthorized modification to the device, this declaration becomes invalid.

DESIGNATION MAS-100 ISO NT
APPLICATION MICROBIOLOGICAL AIR SAMPLER

RELEVANT LEGISLATION

Electrical Equipment (Safety) Regulations 2016	Low voltage directive
Electromagnetic Compatibility Regulations 2016	Electromagnetic compatibility
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012	RoHS
The Waste Electrical and Electronic Equipment Regulations 2013	WEEE
UK REACH	REACH

APPLIED STANDARDS

EN 61010-1: 2020-3	IEC 61000-3-2:2014
IEC 61326-1: 2020-10	IEC 61000-3-3:2013
EN 55011: 2016, class B	EN 61000-3-2:2014
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DESIGNATION MAS-100 ISO NT
APPLICATION MICROBIOLOGICAL AIR SAMPLER

RELEVANT DIRECTIVES

SJ/T11363-2006 P.R. of China RoHS

The instrument is compliant with the Chinese RoHS regulation SJ/T11363 2006.

The table below lists the instruments' hazardous substances.

部件名称 Component name	有害物质或元素 Hazardous substances or elements					
	铅 Pb	汞 Hg	镉 Cd	六价铬 Cr(VI)	多溴联苯 PBB	多溴联苯醚 PBDE
Main PCB	o	o	o	o	o	o
Connector PCB	o	o	o	o	o	o
Processor PCB	x	o	o	o	o	o

O: 表示该有毒有害物质在该部件所有均质材料中的含量均在SJ/T11363-2006 标准规定的限量要求以下

X: 表示该有毒有害物质至少在该部件的某一均质材料中的含量超出SJ/T11363-2006 标准规定的限量要求
(企业可在此处, 根据实际情况对上表中打“X”的技术原因进行进一步说明。)

O: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006

X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006 (Company can explain technical reason to mark «X»).

MANUFACTURER

Company	MBV AG	Signatory	Beat Glauser
Address	Industriestrasse 9 CH-8712 Stäfa Switzerland	Function	CTO
		Date	13.01.2023
		Signature	

COMPLIANCE DECLARATION

REACH/SVHC

To the best of our knowledge, we hereby confirm that all products listed in the following table comply with all the requirements of the European Union Regulation (EC) 1907/2006 governing the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and do not contain any of the substances listed in the Candidate List of Substances of Very High Concern for Authorisation.

If an ingredient of a component of one of our products should be placed on this list, we would inform you immediately.

FINAL PRODUCT

NAME	TYPE
MAS-100 Iso NT	All Types

EXEMPTION

PART	SUBSTANCE NAME	CAS NUMBER	CONCENTRATION
Prozessor PCB	Lead	7439-92-1	0.2000%

Name: Beat Glauser

Date: 13.01.2023

Signature: 

COMPLIANCE DECLARATION

ROHS 2015/863/EU

To the best of our knowledge, we hereby confirm that all products listed in the following table meet the requirements of the EU Directive 2015/863/EU "Restriction of the use of certain Hazardous Substances in electrical and electronic equipment".

We gather information independently and inform you immediately in case of any relevant change.

FINAL PRODUCT

NAME	TYPE
MAS-100 Iso NT	All Types

EXEMPTION

PART	SUBSTANCE NAME	CONCENTRATION	EXEMPTION
Prozessor PCB	Lead and lead compounds	0.2000%	7(c)-I - Electrical and electronic components containing lead in a glass or ceramic other than dielectric ceramic in capacitors, e.g. piezoelectronic devices, or in a glass or ceramic matrix compound

Name: Beat Glauser

Date: 13.01.2023

Signature: 