

EU DECLARATION OF CONFORMITY



We.

MBV AG, CH 8712 Stäfa (Switzerland)

declare under our sole responsibility that the product

MAS-100 Sirius®

Following the provisions of Directive(s) and Regulations

- 2014/35/EU (low voltage)
- 2014/30/EU (electromagnetic compatibility)
- 2013/35/EU (human exposure restrictions for electromagnetic fields)
- 2011/65/EU (restriction of the use of hazardous substances RoHS)
- 2012/19/EU (waste electrical and electronic equipment WEEE)
- REG (EC) 1907/2006 (registration, evaluation, authorisation and restriction of chemicals – REACH)
- REG (EU) 2023/1542 (batteries)

To which this declaration relates is in conformity with the following standards

- EN 61010-1:2010/A1:2019
- EN 61326-1:2021
- EN 62311:2019
- EN 55011:2016/A11:2020
- EN 62133-2:2017/A1:2021

Signatory Beat Glauser

Function CTO

Date 2025-07-09

Signature 3. Alausur

DECLARATION OF CONFORMITY

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

DESIGNATION MAS-100 SIRIUS®

APPLICATION MICROBIAL AIR SAMPLER

RELEVANT DIRECTIVES and REGULATIONS

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

47 CFR Part 15 United States of Radio frequency devices

America

APPLIED STANDARDS

IEC 61010-1:2010/AMD1:2016 UL 61010-1 + A1

IEC 61326-1:2020 CAN/CSA C22.2 No. 61010-1 + A1

CISPR 11:2015 + AMD1:2016 + AMD2:2019

GAMP

Developed and validated according to GAMP 5.

Usage as category 3 recommended (off-the-shelf product).

MANUFACTERER

Company MBV AG Signatory Beat Glauser

Address Industriestrasse 9 Function CTO

CH-8712 Stäfa Date 2025-07-09 Switzerland

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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 SIRIUS®

APPLICATION MICROBIAL 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
threaded sleeves from copper alloy (brass)	×	0	0	0	0	0

- 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 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所用均质材料之一中含量超出 SJ/T11363-2006 规定的限量要求(公司可对标记"X"的技术原因进行说明)
- 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»).

MANUFACTERER				
Company	MBV AG	Signatory	Beat Glauser	
Address	Industriestrasse 9	Function	СТО	
	CH-8712 Stäfa Switzerland	Date	2025-07-09	
	Switzerland	Signature	3. Glauser	

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).

- The product contains the Substance of Very High Concern (SVHC) lead (CAS No. 7439-92-1) in a concentration above 0.1% w/w in the threded sleeves manufactured from copper alloy (brass).
- As required under Article 33(1), we inform our downstream users of the presence of this SVHC.
- The use of lead in this application is technically justified due to its function in machinable brass.
- Notification to the ECHA is not required as the SVHC is not intended to be released under normal or foreseeable use and the total amount of that SVHC in all articles does not exceeds 1 tonne/year
- No other SVHCs above 0.1% w/w are present.

FINAL PRODUCT

NAME	MBV ART. NR.	MERCK ART. NR.
MAS-100 Sirius®	200515 201371	1178800001 1178810001

Name Beat Glauser

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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", with the exception listed below:

- The threaded sleeves are manufactured from copper alloy (brass) containing lead up to 3.5% by weight, which exceeds the general restriction of 0.1% for lead.
- This use is explicitly covered by Annex III Exemption 6(c) of the RoHS Directive: "Copper alloys containing up to 4 % lead by weight"

Therefore, the product is RoHS-compliant under exemption 6(c).

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

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COMPLIANCE DECLARATION DIRECTIVE 2013/35/EU

Technical Evaluation

- The instrument contains no intentional radio frequency transmitters, such as WiFi, Bluetooth, RFID, NFC, or cellular modules.
- All components were covered under applicable electromagnetic compatibility (EMC) testing.
- The product was successfully tested for EMC emission in accordance with the following harmonised standard: EN 55011:2016/A11:2020

Based on compliance with EMC Class B emission limits, the absence of any intentional EMF sources and a normal use at typical operator distances, the equipment is not expected to produce electromagnetic fields exceeding the exposure limits defined in EN 62311:2019.

No further EMF exposure measurements are required. Conformity with EN 62311:2019 is hereby confirmed to the best of our knowledge.

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