

Suppliers declaration of conformity

We

Mabtech AB

declare that the SDoC is issued under our sole responsibility and belongs to the following product:

Type of product: FluoroSpot/ELISpot/FociSpot reader and ELISpot reader

Apparatus model/product: Mabtech IRIS™ 2 FluoroSpot/ELISpot/FociSpot reader and Mabtech ASTOR™ 2 ELISpot reader

Product number: 2000 and 2001

Intended use - Mabtech IRIS™ 2: Detection of secreting cells in ELISpot and FluoroSpot assay. Detection of virus-infected cells (foci) in FociSpot assay. For research use only.

Intended use – Mabtech ASTOR™ 2: Detection of secreting cells in ELISpot assay. For research use only.

Object of the declaration



Mabtech IRIS™ 2



Mabtech ASTOR™ 2

Signed for and on behalf of Mabtech AB:

Nacka Strand

2023-09-15

Place of issue

Date of issue



Jan Wahlström, CEO

www.mabtech.com

Contact Details

Email: mabtech@mabtech.com
Phone: +46 8 716 27 00
Fax: +46 8 716 27 01

Mailing Address

Mabtech AB
Box 1233
SE-131 28 Nacka Strand
Sweden

Visiting Address

Mabtech AB
Augustendalstorget 9
SE-131 52 Nacka Strand
Sweden

Organisation/Finance

Organisation no: 556 276-8225
VAT no: SE556276822501

References

The following standards have been applied:

Title, Edition, Date of standard:

EMC (US)

<u>Standard</u>	<u>Description</u>
CFR 47 Part 2 2019-10-01 (\$ 2.906 SDoC)	Code of Federal Regulations Title 47: Telecommunication Part 2 - Frequency allocations and radio treaty matters; General rules and regulations
CFR 47 Part 15 (Class B) 2019-10-01	Code of Federal Regulations Title 47: Telecommunication Part 15 - Radio frequency devices

FCC Compliance Statement:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: **(1)** This device may not cause harmful interference, and **(2)** this device must accept any interference received, including interference that may cause undesired operation.

Responsible Party – U.S. Contact Information:

Mabtech, Inc.
M.E.B. Suite 220, 3814 West Street
OH 45227 Cincinnati
United States
Tel: +1 513 871 4500 Toll free: +1 866 ELI-SPOT
Fax: +1 513 871 7353
Email: mabtech.usa@mabtech.com

EMC (CA)

<u>Standard</u>	<u>Description</u>
ICES-003 (Class B) Issue 7:2020-10-15	Information Technology Equipment (including Digital Apparatus)

Quality Management Systems (QMS)

<u>Standard</u>	<u>Description</u>
ISO 13485:2016 Edition 3:2016-03-02	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
ISO 9001:2015 Edition 5:2015-09-15	Quality management systems – Requirements

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International Safety Standards

<u>Standard</u>	<u>Description</u>
IEC 61010-2-101* 2:2015-01-23	Safety requirements for electrical equipment for measurement, Edition control and laboratory use - Part 2-101: Particular requirements for <i>in vitro</i> diagnostic (IVD) medical equipment
IEC 61010-1 Edition 3:2010-06-10 +A1:2016-12-16	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 62471 Edition 1:2006-07-26	Photobiological safety of lamps and lamp systems

International EMC Standards/Test Methods

<u>Standard (Limit/Levels)</u>	<u>Description</u>
IEC 61326-1 (Table 2) Edition 3:2020-10-26 Edition 2:2012-07-10	Electrical equipment for measurement, control and laboratory use EMC requirements - Part 1: General requirements
IEC 61326-2-6* Edition 3:2020-10-27 Edition 2:2012-07-10	Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 2-6: Particular requirements - <i>In vitro</i> diagnostic (IVD) medical equipment
CISPR 11 (Class B) Edition 6:2015-06-09 +A1:2016-06-23 +A2:2019-01-18	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
IEC 61000-3-2 (Class A) Edition 5:2018-01-26 +A1:2020-07-14 Edition 4:2014-05-26	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
IEC 61000-3-3 Edition 3:2013-05-14 +A1:2017-05-18 +A2:2021-03-25	Electromagnetic compatibility (EMC) - Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection

* IVD standards for Safety & EMC only for Mabtech IRIS™ 2 FluoroSpot/ELISpot/FociSpot reader

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<u>Test Methods (Level/Class)</u>	<u>Description</u>
ANSI C63.4-2014 Edition 7:2014-06-20 +ANSI C63.4a-2017 Amendment:2017-10-13	American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz
IEC 61000-4-2 (Level 2/3) Edition 2:2008-12-09	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
IEC 61000-4-3 (Level 3)** Edition 3:2006-02-07 A1: 2007-11-07 A2: 2010-03-10	Electromagnetic Compatibility (EMC) - Part 4-3: Testing and measurement techniques -Radiated, radio-frequency, electromagnetic field immunity test
IEC 61000-4-4 (Level 3) Edition 3:2012-04-30	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
IEC 61000-4-5 (Level 3/4) Edition 2:2005-11-29 +A1: 2017-08-04	Electromagnetic Compatibility (EMC) Part 4-5: Testing and measurement techniques - Surge immunity test
IEC 61000-4-6 (Level 3) Edition 4:2013-10-23	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
IEC 61000-4-8 (Level 4) Edition 2:2009-09-03	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity
IEC 61000-4-11 (Class 2/3) Edition 2: 2004-03-24 +A1: 2017-05-18	Electromagnetic Compatibility (EMC) – Part 4-11: Testing and measurement techniques. Voltage dips, short interruptions and voltage variations immunity tests
IEC 61000-4-20 (Level 3)*** Edition 2:2010-08-31	Electromagnetic compatibility (EMC) – Part 4-20: Testing and measurement techniques – Emission and immunity testing in transverse electromagnetic (TEM) waveguides

** Test method only for Mabtech IRIS™ 2 FluoroSpot/ELISpot/FociSpot reader

*** Test method only for Mabtech ASTOR™ 2 ELISpot reader

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Products

<u>Apparatus model</u>	<u>Product number</u>	<u>Type of product</u>
Mabtech IRIS™ 2 FluoroSpot/ELISpot/FociSpot reader	2000	FluoroSpot/ELISpot/FociSpot reader
Mabtech ASTOR™ 2 ELISpot reader	2001	ELISpot reader
Mabtech Apex™ Software for MAC/PC	2101-0001/2101-0003	Software used with Mabtech IRIS™ 2 / Mabtech ASTOR™ 2
Power Cord	2700-0000	Power cord used with Mabtech IRIS™ 2 / Mabtech ASTOR™ 2 – Variants: EU, UK, Switzerland, Israel, North America, Brazil, China, India, South Africa or AU/NZ
USB3 Cable	ECA0013/2000	USB cable used with Mabtech IRIS™ 2 / Mabtech ASTOR™ 2 (CBL USB 3.0 A/B LSZH)
Ethernet Cable	2700-0001	Ethernet-/network cable used with Mabtech IRIS™ 2 (CAT6A SHIELDED RJ45 BLACK 7)

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