

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, ELISpot reader and Multiplex instrument.

Apparatus model/product: Mabtech IRIS™ FluoroSpot/ELISpot/FociSpot reader, Mabtech ASTOR™ ELISpot reader, and Mabtech EYRA™ Multiplex instrument.

Product number: 2000, 2001, 2002

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

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

Intended use – Mabtech EYRA™: Detection of analytes in solution in bead-based assay. For research use only.

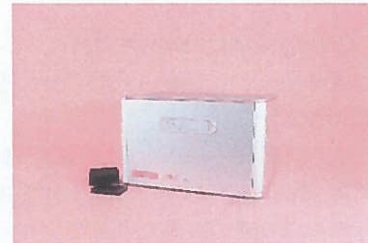
Object of the declaration



FluoroSpot/ELISpot/FociSpot reader
Mabtech IRIS™



ELISpot reader
Mabtech ASTOR™



Multiplex instrument
Mabtech EYRA™

Signed for and on behalf of Mabtech AB:

Nacka Strand

2025-06-27

A handwritten signature in blue ink, reading 'P. Keefe'.

Place of issue

Date of issue

Phill Keefe, CEO

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Contact Details

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Organisation/Finance

Organisation no: 556 276-8225
VAT no: SE556276822501

References

The following standards have been applied:

Title, Edition, Date of standard:

EMC & Laser Safety (US)

<u>Standard</u>	<u>Description</u>
CFR 21 Part 1040 2023-04-01	Code of Federal Regulations Title 21 - Food and Drugs Chapter I - FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED) Subchapter J - RADIOLOGICAL HEALTH PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS
§ 1040.10	Laser products
§ 1040.11	Specific purpose laser products.
CFR 47 Part 2 2022-10-01 (\$ 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)* 2022-10-01	Code of Federal Regulations Title 47: Telecommunication Part 15 - Radio frequency devices
§ 15.107	Conducted limits
§ 15.109	Radiated emission limits

** Class A for Conducted Emission on the AC port but Class B for Radiated Emission for Mabtech EYRA™ with two PSUs.*

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:

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EMC & Laser Safety (CA)

<u>Standard</u>	<u>Description</u>
ICES-Gen Issue 2:2024-02-23	General Requirements for Compliance of Interference-Causing Equipment
ICES-003 Issue 7:2020-10-15	Information Technology Equipment (including Digital Apparatus)
CAN ICES(B) / NMB(B)*	
CAN ICES(A) / NMB(A)**	
REDR C1370 2022-09-27	Radiation Emitting Devices Regulations

* Class B for both Conducted & Radiated Emission for Mabtech IRIS™ & Mabtech ASTOR™

** Class A for Conducted Emission on the AC port but Class B for Radiated Emission for Mabtech EYRA™ with two PSUs.

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

International Safety Standards

<u>Standard</u>	<u>Description</u>
IEC 61010-2-101* Edition 2:2015-01-23	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-1 Edition 3:2010-06-10 +A1:2016-12-16 +A1 C1:2019-03-21	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
IEC 61010-2-081*** Edition 3:2019-02-12	Safety requirements for electrical equipment for measurements, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

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IEC 62471**
Edition 1:2006-07-26

Photobiological safety of lamps and lamp systems

IEC 60825-1***
Edition 3:2014-05-05

Safety of laser products - Part 1: Equipment classification and requirements

* IVD standard for Safety, only for Mabtech IRIS™

** Safety standard, only for Mabtech IRIS™ & Mabtech ASTOR™

*** Safety standards, only for Mabtech EYRA™

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* (Table 101) 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 standard for EMC, only for Mabtech IRIS™

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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 3:2014-05-15 +A1:2017-08-04	Electromagnetic Compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
IEC 61000-4-6 (Level 3) Edition 5:2023-06-06 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 3:2020-01-28 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 for equipment with input current up to 16 A per phase
IEC 61000-4-20 (Level 3)** Edition 3:2022-02-18 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™ & Mabtech EYRA™

** Test method only for Mabtech ASTOR™

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Products

<u>Apparatus model</u>	<u>Product number</u>	<u>Type of product</u>
Mabtech IRIS™ FluoroSpot/ELISpot reader	2000	FluoroSpot/ELISpot reader
Mabtech ASTOR™ ELISpot reader	2001	ELISpot reader
Mabtech EYRA™ Multiplex instrument	2002	Multiplex instrument
Mabtech Apex™ Software	2101-0001/2101-0003	Software used with Mabtech IRIS™ / Mabtech ASTOR™
Mabtech Opal™ Software	2101-0006	Software used with Mabtech EYRA™
Power Cord	2700-0000	Power cord used with Mabtech IRIS™ / Mabtech ASTOR™ & Mabtech EYRA™ – 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™ / Mabtech ASTOR™ & Mabtech EYRA™ (CBL USB 3.0 A/B LSZH)
Ethernet Cable	2700-0001	Ethernet-/network cable used with Mabtech IRIS™ (CAT6A SHIELDED RJ45 BLACK 7)

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