

CE EU declaration of conformity

We

Mabtech AB

declare that the DoC 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.

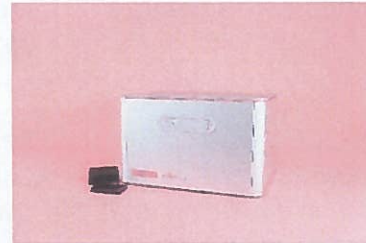
Object of the declaration



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

Place of issue

Date of issue

Phill Keefe, CEO

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Organisation/Finance

Organisation no: 556 276-8225
VAT no: SE556276822501

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

<u>Directive</u>	<u>Description</u>
<u>2014/30/EU</u> 2014-02-26	Electromagnetic Compatibility (EMC) Directive
<i>Publications in the Official Journal:</i>	
OJ C 246 of 13/07/2018	Publications from the Official Journal of the European Union
OJ L 206 of 05/08/2019	Commission Implementing Decision (EU) 2019/1326
Amendment 15/05/2020	Amendment of 15 May 2020 to Implementing Decision (EU) 2019/1326
Amendment 03/11/2020	Amendment of 3 November 2020 to Implementing Decision (EU) 2019/1326
Amendment 15/03/2021	Amendment of 15 March 2021 to Implementing Decision (EU) 2019/1326
Amendment 07/04/2022	Amendment of 7 April 2022 to Implementing Decision (EU) 2019/1326
Amendment 09/06/2022	Amendment of 9 June 2022 to Implementing Decision (EU) 2019/1326

<u>2014/35/EU</u> 2014-02-26	Low Voltage Directive (LVD)
<i>Publications in the Official Journal:</i>	
OJ L, 2023/2723, 13/12/2023	Commission Implementing Decision (EU) 2023/2723 of 6 December 2023
Amendment 19/04/2024	Amendment of 19 April 2024 to Implementing Decision (EU) 2023/2723

<u>2011/65/EU</u> 2011-06-08	Restriction of Hazardous Substances (RoHS) Directive Current consolidated version: 01/08/2024
<i>Directive amending RoHS Directive:</i>	
OJ L 305 of 15/11/2017	2017 Directive amending RoHS Directive
<i>Publications in the Official Journal:</i>	
OJ L 155 of 15/05/2020	Commission Implementing Decision (EU) 2020/659

Quality Management Systems (QMS)

<u>Standard</u>	<u>Description</u>
EN ISO 13485:2016 Edition 4:2016-03-02 +A11:2021-09-08	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 9001:2015 Edition 4:2015-09-15	Quality management systems – Requirements (ISO 9001:2015)

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Risk Assessment

<u>Directive</u>	<u>Description</u>
2014/30/EU 02014L0030 of 11/09/2018	Electromagnetic Compatibility (EMC) Directive of 2014-02-26 Official Journal of the European Union (Consolidated version) ANNEX II - MODULE A: INTERNAL PRODUCTION CONTROL 3. Technical documentation
2014/35/EU OJ L 96 of 29/03/2014	Low Voltage Directive (LVD) of 2014-02-26 Official Journal of the European Union ANNEX III - MODULE A: 2. Technical documentation.

The following standards have been applied:

Title, Edition, Date of standard:

Safety (Low Voltage)

<u>Standard</u>	<u>Description</u>
EN 61010-2-101* Edition 2:2017-02-24	Safety requirements for electrical equipment for measurements, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (IEC 61010-2-101:2015)
EN 61010-1 Edition 3:2010-10-15 +A1:2019-02-22 +A1:2019/AC:2019-04-26	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (IEC 61010-1:2010)
EN IEC 61010-2-081*** Edition 3:2020-05-22	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 (IEC 61010-2-081:2019)
EN 62471** Edition 1:2008-09-12	Photobiological safety of lamps and lamp systems (IEC 62471:2006, modified)
EN 60825-1*** Edition 5:2014-08-08 +A11:2021-02-19	Safety of laser products - Part 1: Equipment classification and requirements (IEC 60825-1:2014)

* IVD standard for Safety, only for Mabtech IRIS™

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

*** Safety standards, only for Mabtech EYRA™

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EMC

<u>Standard (Limit/Level)</u>	<u>Description</u>
EN IEC 61326-1 (Table 2) Edition 4:2021-06-04 Edition 3:2013-01-11	Electrical equipment for measurement, control and laboratory use EMC requirements - Part 1: General requirements (IEC 61326-1:2020 & 2012)
EN IEC 61326-2-6** Edition 3:2021-06-04 Edition 2:2013-05-03 (Table 101)	Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 2-6: Particular requirements - <i>In vitro</i> diagnostic (IVD) medical equipment (IEC 61326-2-6:2020 & 2012)
CENELEC EN 55011 (Class B)* Edition 5: 2016-04-01 +A1:2017-04-21 +A11:2020-03-06 +A2:2021-04-09	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement (CISPR 11:2015, modified)
EN IEC 61000-3-2 (Class A) Edition 5:2019-03-01 +A1:2021-04-09 Edition 4:2014-08-22	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (IEC 61000-3-2:2018 & 2014)
EN 61000-3-3 Edition 3:2013-08-23 +A1:2019-08-02 +A2:2021-11-05 +A2/AC:2022-01-28	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 (IEC 61000-3-3:2013)

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

** *IVD standard for EMC, only for Mabtech IRIS™*

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<u>Test Methods (Level/Class)</u>	<u>Description</u>
EN 61000-4-2 (Level 2/3) Edition 2:2009-03-31	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test (IEC 61000-4-2:2008)
EN 61000-4-3 (Level 3)* 3:2006-05-19 A1:2008-02-13 A2:2010-07-09	Electromagnetic Compatibility (EMC) - Part -3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test (IEC61000-4-3:2006) Edition
EN 61000-4-4 (Level 3) Edition 3:2012-11-09	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test (IEC 61000-4-4:2012)
EN 61000-4-5 (Level 3/4) Edition 3:2014-08-22 +A1:2017-11-24	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test (IEC 61000-4-5:2014)
EN IEC 61000-4-6 (Level 3) Edition 5:2023-07-28 Edition 4:2014-02-21	Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields (IEC 61000-4-6:2023 & 2013)
EN 61000-4-8 (Level 4) Edition 2:2010-02-12	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity (IEC 61000-4-8:2009)
EN IEC 61000-4-11 (Class 2/3) Edition 3:2020-03-27 Edition 2:2004-08-03 +A1:2017-08-04	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 61000-4-11:2020 & 2004)
EN IEC 61000-4-20** Edition 3:2022-04-01 Edition 2:2010-11-05 (Level 3)	Electromagnetic compatibility (EMC) - Part 4-20: Testing and measurement techniques - Emission and immunity testing in transverse electromagnetic (TEM) waveguides (IEC 61000-4-20:2022 & 2010)

* Test method only for Mabtech IRIS™ & Mabtech EYRA™

** Test method only for Mabtech ASTOR™

RoHS

<u>Standard</u>	<u>Description</u>
CENELEC EN IEC 63000 Edition 1:2018-12-07	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances (IEC 63000:2016)

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Products

<u>Apparatus model</u>	<u>Product number</u>	<u>Type of product</u>
Mabtech IRIS™ FluoroSpot/ELISpot/FociSpot reader	2000	FluoroSpot/ELISpot/FociSpot 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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