

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 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

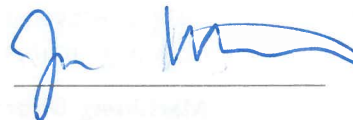
Signed for and on behalf of Mabtech AB:

Nacka Strand

2023-09-15

Place of issue

Date of issue



Jan Wahlström, CEO

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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>	Electromagnetic Compatibility (EMC) Directive
2014-02-26	
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
Amendment 09/01/2022	Amendment of 9 January 2023 to Implementing Decision (EU) 2019/1956
<u>2014/35/EU</u>	Low Voltage Directive (LVD)
2014-02-26	
OJ C 326 of 14/09/2018	Publications from the Official Journal of the European Union
OJ L 306 of 26/11/2019	Commission Implementing Decision (EU) 2019/1956
Amendment 31/07/2020	Amendment of 31 July 2020 to Implementing Decision (EU) 2019/1956
Amendment 27/11/2020	Amendment of 27 November to Implementing Decision (EU) 2019/1956
Amendment 17/06/2021	Amendment of 17 June 2021 to Implementing Decision (EU) 2019/1956
Amendment 20/12/2021	Amendment of 20 December 2021 to Implementing Decision (EU) 2019/1956
Amendment 03/03/2022	Amendment of 3 March 2022 to Implementing Decision (EU) 2019/1956
Amendment 04/05/2022	Amendment of 4 May 2022 to Implementing Decision (EU) 2019/1956
<u>2011/65/EU</u>	Restriction of Hazardous Substances Directive (RoHS)
2011-06-08	
OJ L 137 of 04/06/2015	Commission Delegated Directive (EU) 2015/863 (RoHS 3)
OJ L 305 of 15/11/2017	Amending Annex II to Directive 2011/65/EU
OJ L 155 of 15/05/2020	2017 Directive amending RoHS Directive
	Commission Implementing Decision (EU) 2020/659
<u>2006/42/EC</u>	Machinery Directive (MD)
2006-05-17	

Quality Management Systems (QMS)

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<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)

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 <i>in vitro</i> diagnostic (IVD) medical equipment (IEC 61010-2-101:2015)
EN 61010-1 Edition 3:2010-10-15 +A1:2019-02-22	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (IEC 61010-1:2010)
EN 62471 Edition 1:2008-09-12	Photobiological safety of lamps and lamp systems (IEC 62471:2006, modified)

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 & 2013)
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	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per

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+A1:2021-04-09
Edition 4:2014-08-22

phase) (IEC 61000-3-2:2018)

EN 61000-3-3
Edition 3:2013-08-23
+A1:2019-08-02
+A2:2021-11-05

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)

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

<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 2:2006-11-15 +A1:2017-11-24	Electromagnetic Compatibility (EMC) Part 4-5: Testing and measurement techniques - Surge immunity test (IEC 61000-4-5:2005)
EN 61000-4-6 (Level 3) 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 61000-4-6:2013)
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 61000-4-11 (Class 2/3) 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 (IEC 61000-4-11: 2004)
EN 61000-4-20 (Level 3)*** Edition 2:2010-11-05	Electromagnetic compatibility (EMC) - Part 4-20: Testing and measurement techniques - Emission and immunity testing in transverse electromagnetic (TEM) waveguides (IEC 61000-4-20:2010)

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

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

RoHS

<u>Standard</u>	<u>Description</u>
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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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