

EU Declaration of Conformity

To IVD REGULATION (EU) 2017/746



Legal Manufacturer's Name: Fa-Tech Diagnostics Europe

Legal Manufacturer's Address: 't Holland 31, 6921 GX, Duiven, The Netherlands

SRN (Single Registration Number): NL-MF-000006058

Fa-Tech Diagnostics Europe declares that the In Vitro Diagnostic Medical Devices listed in this declaration are in conformity with all applicable provisions of Council Regulation (EU) 2017/746 of 5 April 2017 on In Vitro Diagnostic Medical Devices and are therefore entitled to bear the CE Mark.

Product and Trade Name	Embedding and Biopsy Cassettes
Intended Purpose	Cassettes are designed to safely and securely contain excised tissue during tissue processing, embedding, and sectioning for diagnostic use.
Classification & Classification Rules	Class A, Rule 5, Indent (c)
Conformity Assessment Route	In accordance with Article 17 and Annex IV of IVDR 2017/746
Product Number	See Appendix I – Device Information
Basic UDI-DI	872061519FAT0014Z
Nomenclature	GMDN 62970, Histological cassette IVD
Initial CE Release Date	2019
Authorized Representative Name and Address	NA
Authorized Representative SRN	NA

We hereby declare under our sole responsibility that these products conform with the relevant provisions of the EU IVD Regulation 2017/746.

We confirm that the CE-marked IVDs listed in the appendix are manufactured under a controlled and approved Quality Management System that maintains a post market surveillance and vigilance procedure. Each of the listed CE-marked IVD has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the EU IVDR 2017/746 prior to being placed on the market.

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Approved by:



Place of Issue: Kalamazoo, US

Date of Issue: 13-May-2022

Revision: 01

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• Appendix 1 – Device Information:

<u>Product Number</u>	<u>Product Description</u>
110-01-10LM	Laser embedding cassettes in taped stacks (white) 25x40 with hinged lid
110-02-10LM	Laser embedding cassettes in taped stacks (yellow) 25x40 with hinged lid
110-03-10LM	Laser embedding cassettes in taped stacks (blue) 25x40 with hinged lid
110-04-10LM	Laser embedding cassettes in taped stacks (pink) 25x40 with hinged lid
110-05-10LM	Laser embedding cassettes in taped stacks (green) 25x40 with hinged lid
110-06-10LM	Laser embedding cassettes in taped stacks (orange) 25x40 with hinged lid
110-07-10LM	Laser embedding cassettes in taped stacks (grey) 25x40 with hinged lid
110-08-10LM	Laser embedding cassettes in taped stacks (aqua) 25x40 with hinged lid
110-09-10LM	Laser embedding cassettes in taped stacks (lilac) 25x40 with hinged lid
110-10-10LM	Laser embedding cassettes in taped stacks (beige) 25x40 with hinged lid
110-11-10LM	Laser embedding cassettes in taped stacks (ochre) 25x40 with hinged lid
110-12-10LM	Laser embedding cassettes in taped stacks (red) 25x40 with hinged lid
115-01-10LM	Laser embedding cassettes in taped stacks (white) 25x40 with front lid
115-02-10LM	Laser embedding cassettes in taped stacks (yellow) 25x40 with front lid
115-03-10LM	Laser embedding cassettes in taped stacks (blue) 25x40 with front lid
115-04-10LM	Laser embedding cassettes in taped stacks (pink) 25x40 with front lid
115-05-10LM	Laser embedding cassettes in taped stacks (green) 25x40 with front lid
115-06-10LM	Laser embedding cassettes in taped stacks (orange) 25x40 with front lid

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115-07-10LM	Laser embedding cassettes in taped stacks (grey) 25x40 with front lid
115-08-10LM	Laser embedding cassettes in taped stacks (aqua) 25x40 with front lid
115-09-10LM	Laser embedding cassettes in taped stacks (lilac) 25x40 with front lid
115-10-10LM	Laser embedding cassettes in taped stacks (beige) 25x40 with front lid
115-11-10LM	Laser embedding cassettes in taped stacks (ochre) 25x40 with front lid
115-12-10LM	Laser embedding cassettes in taped stacks (red) 25x40 with front lid
210-01-10LM	Laser biopsy cassettes in taped stacks (white) 25x40 with hinged lid
210-02-10LM	Laser biopsy cassettes in taped stacks (yellow) 25x40 with hinged lid
210-03-10LM	Laser biopsy cassettes in taped stacks (blue) 25x40 with hinged lid
210-04-10LM	Laser biopsy cassettes in taped stacks (pink) 25x40 with hinged lid
210-05-10LM	Laser biopsy cassettes in taped stacks (green) 25x40 with hinged lid
210-06-10LM	Laser biopsy cassettes in taped stacks (orange) 25x40 with hinged lid
210-07-10LM	Laser biopsy cassettes in taped stacks (grey) 25x40 with hinged lid
210-08-10LM	Laser biopsy cassettes in taped stacks (aqua) 25x40 with hinged lid
210-09-10LM	Laser biopsy cassettes in taped stacks (lilac) 25x40 with hinged lid
210-10-10LM	Laser biopsy cassettes in taped stacks (beige) 25x40 with hinged lid
210-11-10LM	Laser biopsy cassettes in taped stacks (ochre) 25x40 with hinged lid
210-12-10LM	Laser biopsy cassettes in taped stacks (red) 25x40 with hinged lid
215-01-10LM	Laser biopsy cassettes in taped stacks (white) 25x40 with front lid
215-02-10LM	Laser biopsy cassettes in taped stacks (yellow) 25x40 with front lid
215-03-10LM	Laser biopsy cassettes in taped stacks (blue) 25x40 with front lid
215-04-10LM	Laser biopsy cassettes in taped stacks (pink) 25x40 with front lid

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215-05-10LM	Laser biopsy cassettes in taped stacks (green) 25x40 with front lid
215-06-10LM	Laser biopsy cassettes in taped stacks (orange) 25x40 with front lid
215-07-10LM	Laser biopsy cassettes in taped stacks (grey) 25x40 with front lid
215-08-10LM	Laser biopsy cassettes in taped stacks (aqua) 25x40 with front lid
215-09-10LM	Laser biopsy cassettes in taped stacks (lilac) 25x40 with front lid
215-10-10LM	Laser biopsy cassettes in taped stacks (beige) 25x40 with front lid
215-11-10LM	Laser biopsy cassettes in taped stacks (ochre) 25x40 with front lid
215-12-10LM	Laser biopsy cassettes in taped stacks (red) 25x40 with front lid
315-01-18LM	Laser embedding cassettes in taped stacks (white) 45x40 without lid (require metal lid)
315-02-18LM	Laser embedding cassettes in taped stacks (yellow) 45x40 without lid (require metal lid)
315-03-18LM	Laser embedding cassettes in taped stacks (blue) 45x40 without lid (require metal lid)
315-04-18LM	Laser embedding cassettes in taped stacks (pink) 45x40 without lid (require metal lid)
315-05-18LM	Laser embedding cassettes in taped stacks (green) 45x40 without lid (require metal lid)
315-06-18LM	Laser embedding cassettes in taped stacks (orange) 45x40 without lid (require metal lid)
315-07-18LM	Laser embedding cassettes in taped stacks (grey) 45x40 without lid (require metal lid)
315-08-18LM	Laser embedding cassettes in taped stacks (aqua) 45x40 without lid (require metal lid)
315-09-18LM	Laser embedding cassettes in taped stacks (lilac) 45x40 without lid (require metal lid)
315-10-18LM	Laser embedding cassettes in taped stacks (beige) 45x40 without lid (require metal lid)
315-11-18LM	Laser embedding cassettes in taped stacks (ochre) 45x40 without lid (require metal lid)
315-12-18LM	Laser embedding cassettes in taped stacks (red) 45x40 without lid (require metal lid)
FTML315	Metal lid for laser embedding cassettes 315
815-01-18LM	Laser embedding cassettes in taped stacks (white) 45x40 with integrated lid

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815-02-18LM	Laser embedding cassettes in taped stacks (yellow) 45x40 with integrated lid
815-03-18LM	Laser embedding cassettes in taped stacks (blue) 45x40 with integrated lid
815-04-18LM	Laser embedding cassettes in taped stacks (pink) 45x40 with integrated lid
815-05-18LM	Laser embedding cassettes in taped stacks (green) 45x40 with integrated lid
815-06-18LM	Laser embedding cassettes in taped stacks (orange) 45x40 with integrated lid
815-07-18LM	Laser embedding cassettes in taped stacks (grey) 45x40 with integrated lid
815-08-18LM	Laser embedding cassettes in taped stacks (aqua) 45x40 with integrated lid
815-09-18LM	Laser embedding cassettes in taped stacks (lilac) 45x40 with integrated lid
815-10-18LM	Laser embedding cassettes in taped stacks (beige) 45x40 with integrated lid
815-11-18LM	Laser embedding cassettes in taped stacks (ochre) 45x40 with integrated lid
815-12-18LM	Laser embedding cassettes in taped stacks (red) 45x40 with integrated lid
110-01-10LMI	Laser embedding cassettes in stripped stacks (white) 25x40 with hinged lid
110-02-10LMI	Laser embedding cassettes in stripped stacks (yellow) 25x40 with hinged lid
110-03-10LMI	Laser embedding cassettes in stripped stacks (blue) 25x40 with hinged lid
110-04-10LMI	Laser embedding cassettes in stripped stacks (pink) 25x40 with hinged lid
110-05-10LMI	Laser embedding cassettes in stripped stacks (green) 25x40 with hinged lid
110-06-10LMI	Laser embedding cassettes in stripped stacks (orange) 25x40 with hinged lid
110-07-10LMI	Laser embedding cassettes in stripped stacks (grey) 25x40 with hinged lid
110-08-10LMI	Laser embedding cassettes in stripped stacks (aqua) 25x40 with hinged lid
110-09-10LMI	Laser embedding cassettes in stripped stacks (lilac) 25x40 with hinged lid
110-10-10LMI	Laser embedding cassettes in stripped stacks (beige) 25x40 with hinged lid
110-11-10LMI	Laser embedding cassettes in stripped stacks (ochre) 25x40 with hinged lid

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110-12-10LMI	Laser embedding cassettes in stripped stacks (red) 25x40 with hinged lid
115-01-10LMI	Laser embedding cassettes in stripped stacks (white) 25x40 with front lid
115-02-10LMI	Laser embedding cassettes in stripped stacks (yellow) 25x40 with front lid
115-03-10LMI	Laser embedding cassettes in stripped stacks (blue) 25x40 with front lid
115-04-10LMI	Laser embedding cassettes in stripped stacks (pink) 25x40 with front lid
115-05-10LMI	Laser embedding cassettes in stripped stacks (green) 25x40 with front lid
115-06-10LMI	Laser embedding cassettes in stripped stacks (orange) 25x40 with front lid
115-07-10LMI	Laser embedding cassettes in stripped stacks (grey) 25x40 with front lid
115-08-10LMI	Laser embedding cassettes in stripped stacks (aqua) 25x40 with front lid
115-09-10LMI	Laser embedding cassettes in stripped stacks (lilac) 25x40 with front lid
115-10-10LMI	Laser embedding cassettes in stripped stacks (beige) 25x40 with front lid
115-11-10LMI	Laser embedding cassettes in stripped stacks (ochre) 25x40 with front lid
115-12-10LMI	Laser embedding cassettes in stripped stacks (red) 25x40 with front lid
210-01-10LMI	Laser biopsy cassettes in stripped stacks (white) 25x40 with hinged lid
210-02-10LMI	Laser biopsy cassettes in stripped stacks (yellow) 25x40 with hinged lid
210-03-10LMI	Laser biopsy cassettes in stripped stacks (blue) 25x40 with hinged lid
210-04-10LMI	Laser biopsy cassettes in stripped stacks (pink) 25x40 with hinged lid
210-05-10LMI	Laser biopsy cassettes in stripped stacks (green) 25x40 with hinged lid
210-06-10LMI	Laser biopsy cassettes in stripped stacks (orange) 25x40 with hinged lid
210-07-10LMI	Laser biopsy cassettes in stripped stacks (grey) 25x40 with hinged lid
210-08-10LMI	Laser biopsy cassettes in stripped stacks (aqua) 25x40 with hinged lid
210-09-10LMI	Laser biopsy cassettes in stripped stacks (lilac) 25x40 with hinged lid

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210-10-10LMI	Laser biopsy cassettes in stripped stacks (beige) 25x40 with hinged lid
210-11-10LMI	Laser biopsy cassettes in stripped stacks (ochre) 25x40 with hinged lid
210-12-10LMI	Laser biopsy cassettes in stripped stacks (red) 25x40 with hinged lid
215-01-10LMI	Laser biopsy cassettes in stripped stacks (white) 25x40 with front lid
215-02-10LMI	Laser biopsy cassettes in stripped stacks (yellow) 25x40 with front lid
215-03-10LMI	Laser biopsy cassettes in stripped stacks (blue) 25x40 with front lid
215-04-10LMI	Laser biopsy cassettes in stripped stacks (pink) 25x40 with front lid
215-05-10LMI	Laser biopsy cassettes in stripped stacks (green) 25x40 with front lid
215-06-10LMI	Laser biopsy cassettes in stripped stacks (orange) 25x40 with front lid
215-07-10LMI	Laser biopsy cassettes in stripped stacks (grey) 25x40 with front lid
215-08-10LMI	Laser biopsy cassettes in stripped stacks (aqua) 25x40 with front lid
215-09-10LMI	Laser biopsy cassettes in stripped stacks (lilac) 25x40 with front lid
215-10-10LMI	Laser biopsy cassettes in stripped stacks (beige) 25x40 with front lid
215-11-10LMI	Laser biopsy cassettes in stripped stacks (ochre) 25x40 with front lid
215-12-10LMI	Laser biopsy cassettes in stripped stacks (red) 25x40 with front lid
315-01-18LMI	Laser embedding cassettes in stripped stacks (white) 45x40 without lid (require metal lid)
315-02-18LMI	Laser embedding cassettes in stripped stacks (yellow) 45x40 without lid (require metal lid)
315-03-18LMI	Laser embedding cassettes in stripped stacks (blue) 45x40 without lid (require metal lid)
315-04-18LMI	Laser embedding cassettes in stripped stacks (pink) 45x40 without lid (require metal lid)
315-05-18LMI	Laser embedding cassettes in stripped stacks (green) 45x40 without lid (require metal lid)
315-06-18LMI	Laser embedding cassettes in stripped stacks (orange) 45x40 without lid (require metal lid)
315-07-18LMI	Laser embedding cassettes in stripped stacks (grey) 45x40 without lid (require metal lid)

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315-08-18LMI	Laser embedding cassettes in stripped stacks (aqua) 45x40 without lid (require metal lid)
315-09-18LMI	Laser embedding cassettes in stripped stacks (lilac) 45x40 without lid (require metal lid)
315-10-18LMI	Laser embedding cassettes in stripped stacks (beige) 45x40 without lid (require metal lid)
315-11-18LMI	Laser embedding cassettes in stripped stacks (ochre) 45x40 without lid (require metal lid)
315-12-18LMI	Laser embedding cassettes in stripped stacks (red) 45x40 without lid (require metal lid)
FTML315	Metal lid for laser embedding cassettes 315
615-01-10LMI	Bionet cassettes in stripped stacks (white) 25x40 with front lid
615-02-10LMI	Bionet cassettes in stripped stacks (yellow) 25x40 with front lid
615-03-10LMI	Bionet cassettes in stripped stacks (blue) 25x40 with front lid
615-04-10LMI	Bionet cassettes in stripped stacks (pink) 25x40 with front lid
615-05-10LMI	Bionet cassettes in stripped stacks (green) 25x40 with front lid
615-06-10LMI	Bionet cassettes in stripped stacks (orange) 25x40 with front lid
615-07-10LMI	Bionet cassettes in stripped stacks (grey) 25x40 with front lid
615-08-10LMI	Bionet cassettes in stripped stacks (aqua) 25x40 with front lid
615-09-10LMI	Bionet cassettes in stripped stacks (lilac) 25x40 with front lid
615-10-10LMI	Bionet cassettes in stripped stacks (beige) 25x40 with front lid
615-11-10LMI	Bionet cassettes in stripped stacks (ochre) 25x40 with front lid
615-12-10LMI	Bionet cassettes in stripped stacks (red) 25x40 with front lid
815-01-18LMI	Laser embedding cassettes in stripped stacks (white) 45x40 with integrated lid
815-02-18LMI	Laser embedding cassettes in stripped stacks (yellow) 45x40 with integrated lid
815-03-18LMI	Laser embedding cassettes in stripped stacks (blue) 45x40 with integrated lid
815-04-18LMI	Laser embedding cassettes in stripped stacks (pink) 45x40 with integrated lid
815-05-18LMI	Laser embedding cassettes in stripped stacks (green) 45x40 with integrated lid
815-06-18LMI	Laser embedding cassettes in stripped stacks (orange) 45x40 with integrated lid
815-07-18LMI	Laser embedding cassettes in stripped stacks (grey) 45x40 with integrated lid

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815-08-18LMI	Laser embedding cassettes in stripped stacks (aqua) 45x40 with integrated lid
815-09-18LMI	Laser embedding cassettes in stripped stacks (lilac) 45x40 with integrated lid
815-10-18LMI	Laser embedding cassettes in stripped stacks (beige) 45x40 with integrated lid
815-11-18LMI	Laser embedding cassettes in stripped stacks (ochre) 45x40 with integrated lid
815-12-18LMI	Laser embedding cassettes in stripped stacks (red) 45x40 with integrated lid

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