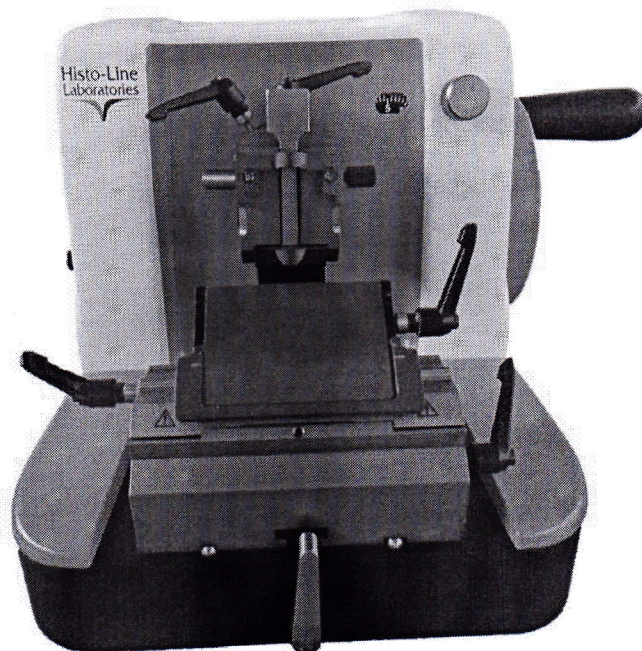


SECTIONING

MR 2258 Manual Rotary Microtome

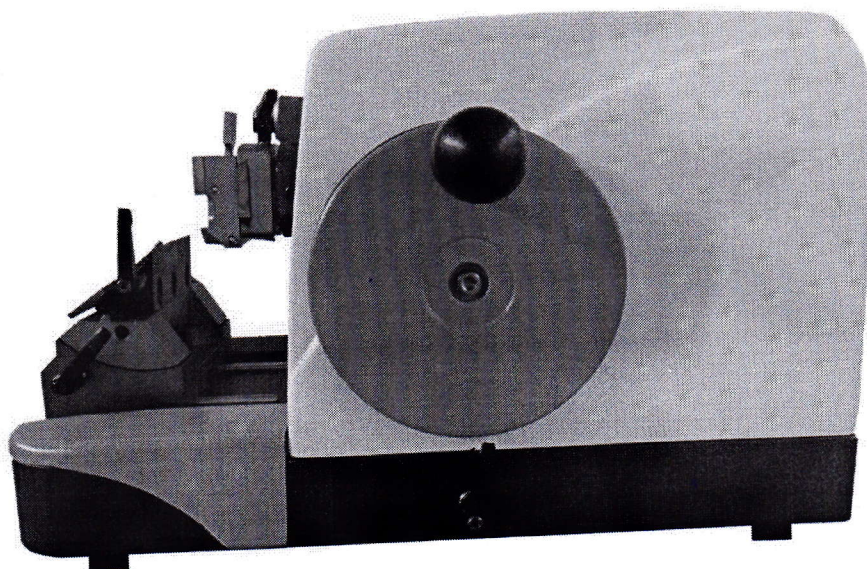
IVD CE



The unit

Simple, reliable, essential, inexpensive. Histo-Line MR 2258 is a manual rotary microtome particularly suitable for cutting of paraffin sections, for normal use in histopathology, but also for the cuts finer used in research.

No extra features but all you need for safe and highly productive sectioning. The microtome is equipped with a precise feed mechanism, vibration-free metal base, advanced blade holder and specimen clamp.



www.histoline.com

SECTIONING

The handwheel is equipped with ergonomic handle for ease of cutting.

The rapid advance handwheel is placed on the left side of the instrument; ergonomic and easy accessibility by the operator.

Block of the handwheel in any position.

Unit is equipped with a "quick-clamp" for quick samples change.

The clamp is suitable for all types of standard cassettes, and is interchangeable by the operator with the ring holder (optional).

Characteristics

- Ergonomic and compact design, fatigue-free for routine operation.
- Excellent section results using both steel knife or disposable blade
- Specimen clamp positioned at 8 X/Y precision orientation system
- Handwheel locked at any position
- Course feed hand wheel systems, closer to user to protect fatigue-free section
- Precise orientation systems, easy to operate
- Red Knife guard to avoid any damage to user, and easy to change disposable blade
- An integrated storage tray (optional) ensures that ancillary tools are on hand at all times
- Large Waste tray, easy to clean and remove

Technical features

Range of the slice thickness: 0 - 60 μ m

Section thickness setting:

0,5 to 2 μ m in 0,5 μ m increments;

2 to 10 μ m in 1 μ m increments;

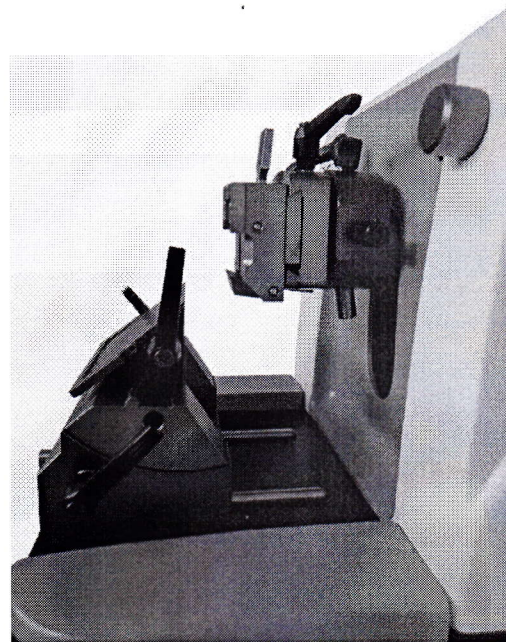
10 to 20 μ m in 2 μ m increments;

20 to 60 μ m in 5 μ m increments

Movable range for the blade holder basal

Forward/Backward: \pm 65 mm

Left / Right: \pm 40 mm



Size and weight

Width: 400 mm

Depth (including tray): 540 mm

Depth (excluding tray): 500 mm

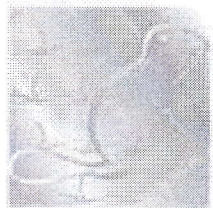
Height of cutting edge: 105 mm

Height: 290 mm

Weight (without accessories): 25 kg

Product	Size	Packaging	Code
Manual Rotary Microtome	Unit	1 pc	MR2258





Reg. Number	14622 A - A	Valid From	2019-02-20
First issue date	2019-02-20	Last change date	2019-02-20
Valid Until	2022-02-19	IAF Sector	29

Quality Management System Certificate ISO 9001:2015

We certify that the Quality Management System of the Organization:

HISTO-LINE LABORATORIES S.r.l.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Design, manufacturing, aftermarket support of diagnostic equipment for research and diagnostic laboratories. Distribution, aftermarket support of diagnostic equipment and in vitro diagnostic devices and technical items for research and diagnostic laboratories

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e
coordinamento di Kiwa Italia
Holding Srl

Via Cadriano, 23

40057 Granarolo dell'Emilia (BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

E-mail: info@kiwacermet.it

www.kiwa.it

HISTO-LINE LABORATORIES S.r.l.

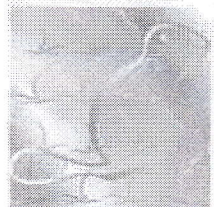
Registered Headquarters

- Viale Giuseppe di Vittorio, 30 20090 Pantigliate (MI) Italia

Certified Sites

- Viale Giuseppe di Vittorio, 30 20090 Pantigliate (MI) Italia





Reg. Number	14622 - M	Valid From	2019-02-20
First issue date	2016-03-10	Last change date	2019-02-20
Valid until	2022-03-09		

Quality Management System Certificate
ISO 13485:2016

We certify that the Quality Management System of the Organization:

HISTO-LINE LABORATORIES S.r.l.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design, manufacturing, aftermarket support of diagnostic equipment for research and diagnostic laboratories.

Distribution, aftermarket support of diagnostic equipment and in vitro diagnostic devices and technical items for research and diagnostic laboratories

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e
coordinamento di Kiwa Italia
Holding Srl

Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

HISTO-LINE LABORATORIES S.r.l.

Registered Headquarters

- Viale Giuseppe di Vittorio, 30 20090 Pantigliate (MI) Italia

Certified Sites

- Viale Giuseppe di Vittorio, 30 20090 Pantigliate (MI) Italia



CERMET



SGQ N° 007A
SGA N° 0100
PRD N° 069B
FSM N° 0041
PRS N° 089C



Viale G.di Vittorio, 30
20090 Pantigliate (MI) Italy

Phone 02.55230061

<http://www.histoline.com>

email: histoline@histoline.com

Data Sheet

Manual Rotary Microtome MR2258



Version 1.1

Histo-Line Laboratories

20/07/2016

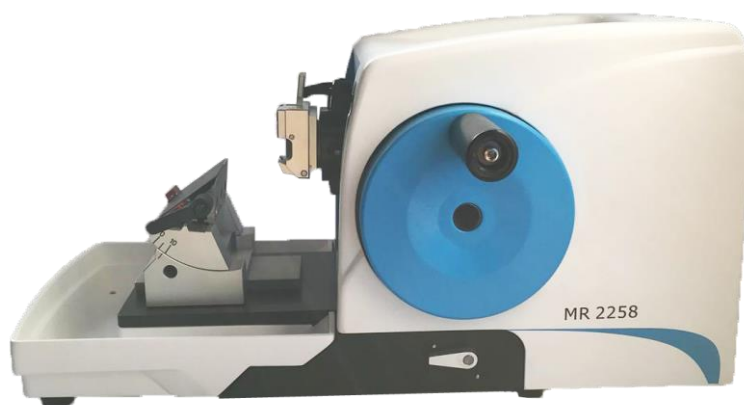
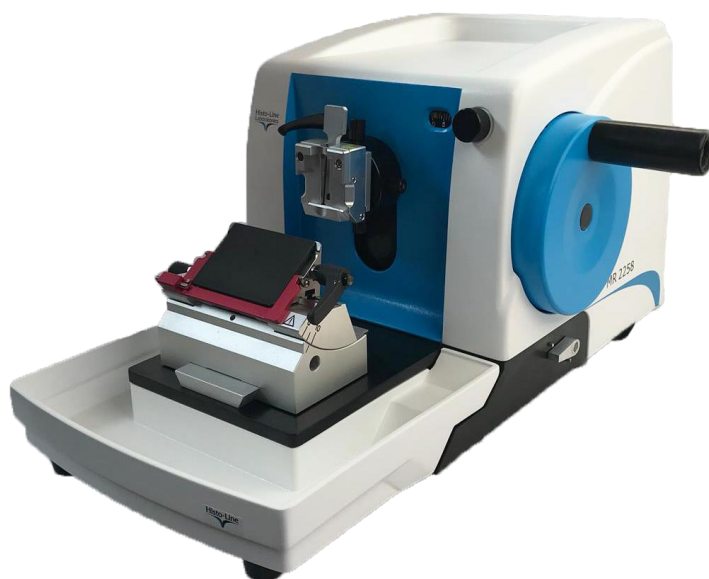
Revision Date:31/10/2018



INDEX

1.Features	3
1.1 Information and specified use.....	4
1.2 Safety and operator comfort.....	4
1.3 Reliability and precision of the cut	5
2. Technical specifications	6
2.1 Thickness section and advancement.....	6
2.2 Control features and functionality	6
2.3 Dimensions and weight	6
2.4 Instrument equipment	7

1.Features



1.1 Information and specified use

The microtome Histo-Line MR2258 is a rotary microtome particularly suitable for manual cutting of paraffin sections, for normal use in clinical histology and histopathology, but also to the finest cuts used in the research field.

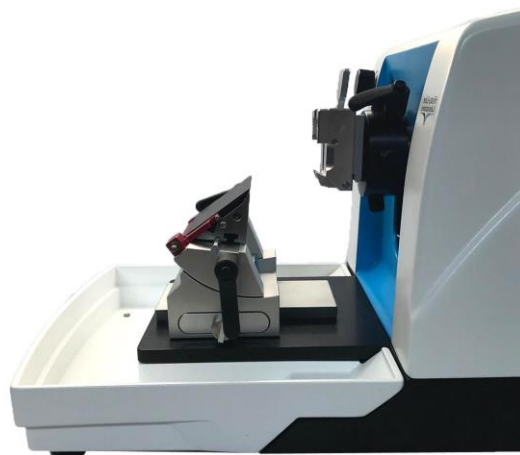
The microtome is coated by a body in a special plastic material resistant to solvents and free of edges thus minimizing the risk of danger to the operators.

1.2 Safety and operator comfort

The flywheel is equipped with ergonomic handle for ease of cutting.

The blocking of the rotation flyer is easily operated and can be accommodated in any position the arm sample holder. It also comes with a mechanical safety catch located under the flying shear.

The upper space of the microtome is equipped with a large area of work surface, covered with a sheath slide that allows the operator to support the accessories needed for cutting (the package of disposable blades, the brush collect slice, etc.)

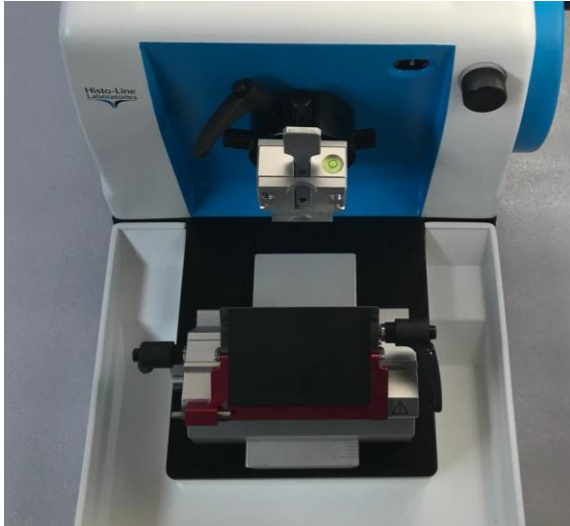


The orientation of the samples is possible in a simple and precise; if the red lights are visible, then the guidance plan is in zero position. The steel clamp is equipped with a device to "clamp" for quick change of the sample and sample holder fixed tilt.

The clamp is suitable for all types of standard biocassettes, and is interchangeable by the operator with the clamp to the biocassettes ring (optional). The sample holder arm is equipped with a mechanism that allows a precise and quick

orientation along the axes x and y. Through the housing port disk sample it is possible to use the clamp for the super mega cassettes, equipped with a dovetail for insertion.

1.3 Reliability and precision of the cut



The microtome MR 2258 has the ability to adjust the cutting thickness and roughing. The holder is universal suitable for disposable blades, features the tilting protection.

The knife holder has the possibility of lateral translation to use the entire edge of the blade without removal of the same. The translation of the knife holder is possible in the three positions corresponding to the length of a standard biocassetta (left, right, center), so as to allow the use of all the microtome knife without loosen the lock.

The microtome is also designed for cutting purposes executions in increments of 1 μm from 1 μm to 20 μm . The micrometer orientation device, located on the left side of the operator, gives an indication of cutting thickness.

The microtome is also designed for cutting purposes executions in increments of 0.5 μm from 0.5 to 2 μm . The structure of the microtome is extremely stable, and is reliable even for execution of cuts particularly hard. Equipped with tray for collecting scrap sections surrounding the front area of work, including the underside of the blade, ergonomic for the operator and removed from the instrument for easy cleaning.

The tray lock is provided at the precise interlocking between the tray it self and the front structure of the microtome.



2. Technical specifications

2.1 Thickness section and advancement

The minimum thickness of cut is set to 0,5 μm .

For the setting "cutting" the setting range is from 0,5 to 60 μm The allowable values and cutting increases are:

- 0,5 to 2 μm in 0,5 μm increments;
- 2 to 10 μm in 1 μm increments;
- 10 to 20 μm in 2 μm increments;
- 20 to 60 μm in 5 μm increments;

The minimum thickness of trimming is set to 0,5 μm .

For the setting "trimming" the setting range is from 0,5 -60 μm . The allowable values and cutting increases are:

- 0,5 to 2 μm in 0,5 μm increments;
- 2 to 10 μm in 1 μm increments;
- 10 to 20 μm in 2 μm increments;
- 20 to 60 μm in 5 μm increments;

2.2 Control features and functionality

Horizontal Specimen feed: 28 \pm 1 mm

Vertical stroke: 60 mm

Maximum sample size (WxHxD): 50 X 60 X 40 mm

Sample orientation: Axes X and Y: 0 to \pm 8 $^{\circ}$, with the zero point.

Z axis: 90 $^{\circ}$ rotation

Movable range for the blade holder basal:

- Forward/Backward: \pm 65 mm
- Left / Right: \pm 40 mm

2.3 Dimensions and weight

Width: 400 mm

Depth (including tray): 540 mm

Depth (excluding tray): 500 mm

Height of cutting edge: 105 mm

Height: 290 mm

Weight (without accessories): 25 kg

2.4 Instrument equipment

Standard accessories

- 1 collection tray sections
- 1 holder blades
- 1 clamp for standard samples
- Manual instructions

Optional accessories

- 1 bottle (50 ml) of microtome oil
- 1 box of 50 disposable blades type S35



DICHIARAZIONE DI CONFORMITA'



EC Declaration of Conformity

PRODUCT LIST:

MR2258	= ULTRA-THIN SEMIAUTOMATIC MICROTOME
MR3000	= MANUAL ROTARY MICROTOME
MRS3500	= SEMIAUTOMATIC MICROTOME
ARM3600	= FULLY MOTORIZED ROTARY MICROTOME
ARM3700	= FULLY MOTORIZED ROTARY MICROTOME
ARM3750	= FULLY MOTORIZED ROTARY MICROTOME
MC3000	= MICROTOME CRYOSTAT
MC4000	= MICROTOME CRYOSTAT
MC5000	= MICROTOME CRYOSTAT
MC5050	= MICROTOME CRYOSTAT
PRO200	= VACUUM TISSUE PROCESSOR
PRO300	= VACUUM TISSUE PROCESSOR
ATS200	= AUTOMATIC SLIDE TISSUE STAINER
ATS2010	= AUTOMATIC SLIDE TISSUE STAINER
SPI00	= CYTOLOGICAL CENTRIFUGE
STP250	= SPIN TISSUE PROCESSOR
STP250-V	= SPIN VACUUM TISSUE PROCESSOR
HL2500	= WATER BATH SLIDE DRYER ALL IN ONE
WB2800	= WATER BATH
WB2900	= TISSUE FLOATING BATH
SD2800	= SLIDE DRYER
TEC3000	= HISTO TRIMMER
TEC2000	= PARAFFIN DISPENSER
TEC2900-1	= MAIN CONSOLE
TEC2900-2	= CRYO CONSOLE
TEC2900-3	= THERMAL CONSOLE
TEC2900-4	= THERMAL CONSOLE DOUBLE FLOOR

LUOGO E DATA
place, date of issue

PANTIGLIATE XX/XX/XXXX

LEGALE RAPPRESENTANTE
LEGAL REPRESENTATIVE





DICHIARAZIONE DI CONFORMITA'

CE

EC Declaration of Conformity

FABBRICANTE
Manufacturer

HISTO-LINE LABORATORIES S.R.L.
VIALE GIUSEPPE DI VITTORIO, 30
20090 PANTIGLIATE (MI) ITALY

PRODOTTO
Product

[NOME PRODOTTO]
[Product Name]

PROCEDURA DI CERTIFICAZIONE
Conformity Assessment Route

Allegato III (escluso par. 6) IVDD 98/79/CEE
Annex III (except sec. 6) MDD 98/79/CEE

DICHIARIAMO ED ASSICURIAMO SOTTO LA NOSTRA RESPONSABILITÀ CHE I PRODOTTI SOPRAMENZIONATI SONO CONFORMI AI REQUISITI ESSENZIALI ELENCATI IN ALLEGATO I DELLA DIRETTIVA IVDD 98/79 CEE RELATIVA AI DISPOSITIVI DIAGNOSTICI IN VITRO.

DICHIARIAMO INOLTRE :

- I DISPOSITIVI NON FANNO PARTE DELLA LISTA A E B DELL' ALLEGATO II DELLA IVDD 98/79 CEE,
- I DISPOSITIVI SONO PROGETTATI, PRODOTTI ED IMMESSI IN COMMERCIO IN ACCORDO AL SISTEMA QUALITÀ AZIENDALE CERTIFICATO ISO 13485,
- L'AZIENDA HA ISTITUITO E TIENE IN ATTO PROCEDURE PER GARANTIRE LA SORVEGLIANZA POST VENDITA COSÌ COME RICHIESTO DALLE AUTORITÀ COMPETENTI EUROPEE,
- TUTTI I DOCUMENTI DI SUPPORTO SONO CONSERVATI PRESSO GLI UFFICI DEL FABBRICANTE.
- I DISPOSITIVI SONO CONFORMI AI SEGUENTI STANDARD ARMONIZZATI: ISO 13485 - ISO 15223 - ISO 14971 - CEI EN 61010 - CEI EN 61326.

We herewith declare and assure under our responsibility that the above mentioned products complies with all the essential requirements listed in Annex I as prescribed in Annex III of the IVDD 98/79 EC Directive.

Furthermore we declare too :

- the devices is not included in the list A and B of Annex II of IVDD 98/79 EC,
- the devices is designed, manufactured and placed on the market according to the Certified Quality System ISO 13485,
- the company have instituted and keep up to date an adequate procedure to guarantee the market surveillance as requested by competent authorities,
- all supporting documentation is retained under the premises of the manufacturer,
- the devices are in accordance this list of harmonized standards : ISO 13485 - ISO 15223 - ISO 14971 - IEC 61010 - IEC 61326.

LA PRESENTE DICHIARAZIONE È VALIDA PER IL DISPOSITIVO NUMERO DI SERIE:
This declaration applies to device serial number

[INT_CODE].XX.XX.XX

LUOGO E DATA
place, date of issue

PANTIGLIATE XX/XX/XXXX

LEGALE RAPPRESENTANTE
LEGAL REPRESENTATIVE

