Especialidades Médicas **Myr** S.L

EC Declaration of Conformity / *Declaración de Conformidad CE*

Manufacturer / *Fabricante* **Especialidades Médicas MYR S.L.**
C/ Lleida 17-23 - 43712 Llorenç del Penedès - Tarragona - Spain

We declare under our own responsibility that the product / *Declaramos bajo nuestra responsabilidad que el producto*

Tissue Processor STP 120-x (x = 1, 2 or 3) / *Procesador de Tejidos STP 120-x (x = 1, 2 or 3)*

meets all the requirements of the following European Directives that are applicable
cumple todos los requisitos aplicables de las siguientes Directivas Europeas

98/79/EC:	In Vitro Diagnostic Devices Directive Classification: General IVD (Other), neither listed in Annex II of IVD 98/79/EC nor IVDs for self-testing purpose
2014/30/EU:	Electromagnetic Compatibility (EMC) Directive
2014/35/EU:	Low Voltage Directive
2011/65/EU:	Restriction of the Use of Hazardous Substances in electrical and electronic equipments (RoHS) Directive

The product is designed and manufactured according to the relevant parts of the following International Standards
El producto está diseñado y fabricado de acuerdo con las partes relevantes de los siguientes estándares

IEC 61010-1: 2010 + A1:2016	**IEC 61010-2-101: 2015**
EN 61326-1: 2013	**EN 61326-2-6: 2013**
EN ISO 14971: 2012	

In addition, the following standards are applied:
Además, la empresa trabaja de acuerdo con las siguientes normas:

ISO 9001-2015:	Quality Management system
ISO 13485-2016:	Medical Devices - Quality Management system

Llorenç del Penedès, 23/10/2019

Francisco Ruiz Robles
Managing Director / *Director General*

Myr

Spin Tissue Processor
STP 120
for tissue infiltration

Devoted to Histology

Spin Tissue Processor STP 120

Myr Spin Tissue Processor STP 120 has been developed to meet the requirements of every single laboratory. The state-of-the-art technology and the unsurpassed processing method of the STP 120 qualifies it as the most successful Spin Tissue Processors ever. More than 3.000 units installed around the world confirm its leading position.

A worldwide unique technique

Tissue processing is a technique that uses alcohols to remove water from tissues and replace it with a medium that allows sectioning of tissue. Several methods are used to achieve this. *Myr* **Spin Tissue Processor STP 120** fulfills it in a patented and unique technique that combines several movements for the tissue to achieve perfect infiltration results. This is possible thanks to the world's best spin processing method.

ROTATIONAL AGITATION. The basket with the cassettes is immersed into the reagent vessel. In this position, the basket turns at 60 rpm and changes the rotational direction every 60 seconds. The rotational agitation achieves a perfect infiltration of tissue, an homogeneous mixture of the reagents and a reduction of processing time. To get better results, the user can start optionally a shaking process.

SHAKING. This movement can be optionally activated on the control panel and allows the basket to perform an up-down movement inside the vessel that combined with the rotational agitation fulfills an helicoidal movement that increases infiltration quality at a high degree of precision. At the end of this process, baskets start centrifuging.

CENTRIFUGING. This function is activated as soon as the infiltration time comes to an end. The basket rises above the reagent's level but rests inside the vessel. For a period of 60 seconds, it starts whirling at 210 rpm and changes the rotational direction every 15 seconds. This process allows the tissue to be optimally drained and avoids carry-over of reagents from one vessel to another.

Tissue processing achieves by this method almost similar results to those obtained with vacuum systems!

Versions

STP 120-1: Standard instrument (basic instrument, 10 reagent vessels, 2 paraffin baths, 1 stainless steel basket for 120 cassettes, 1 tool kit and 1 user manual).

STP 120-2: STP 120-1 + fume extraction system with charcoal filter.

STP 120-3: STP 120-2 + 3rd paraffin station and 2nd basket for another 120 cassettes.

Components and accesories

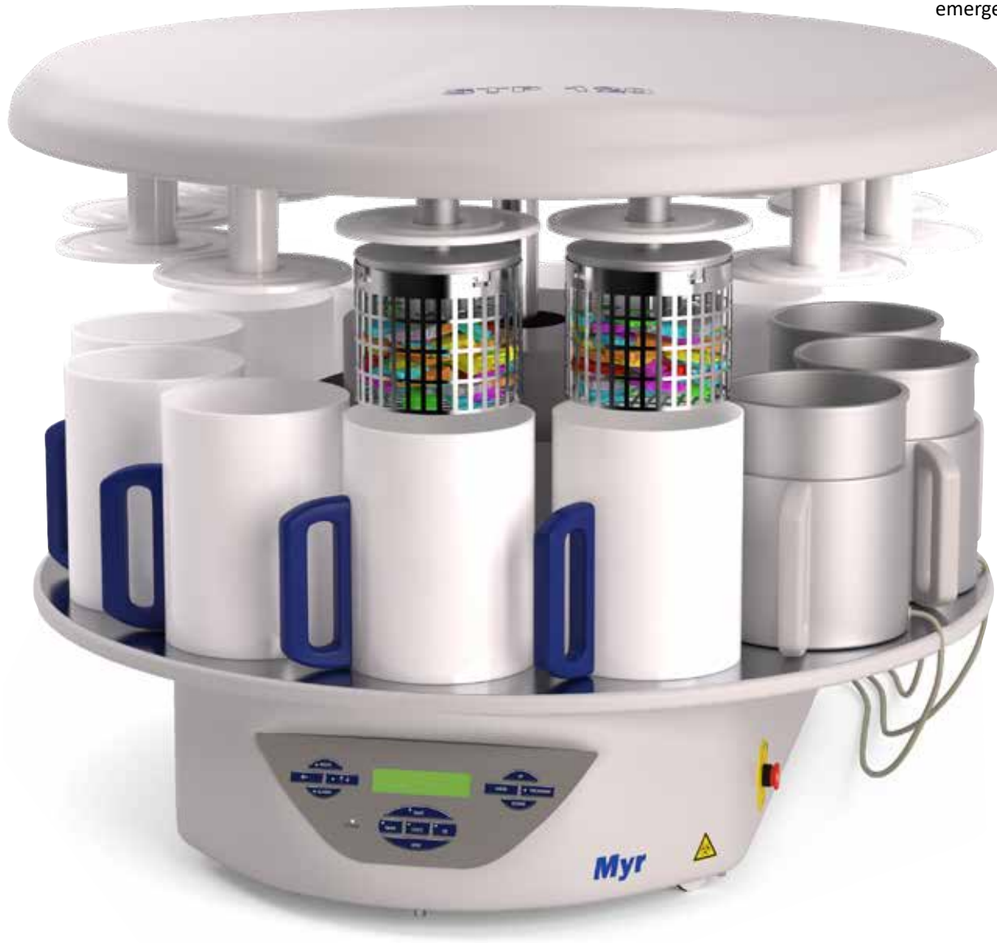
Active charcoal filter

Ergonomic control panel

The buttons of the control panel are arranged ergonomically for easy handling. The LCD display shows all the parameters throughout the process, such as program number, vessel, remaining time, start time, start delay, total duration of the program, rotational agitation and shaking, basket's centrifuging, temperature of paraffin baths, date and time.

Easy handling

The instrument has the capacity to store up to 10 different programs that can be freely set up by the user. Each one of the programs can be started in immediate or delayed mode, without time limit. The instrument can easily be rotated via the four rollers mounted on the base. This allows the user to have fast and safe access to each one of the vessels.



Maximum safety standards for the user and the specimen

The individual cover for each one of the vessels reduces the emission of vapors to a minimum. The STP 120-2 and STP 120-3 versions incorporate a fume extraction system that - through a fan and an active charcoal filter - cleanse the vapors before being discharged into the air.

In case of a power shutdown, the specimens are automatically lowered inside the vessel by means of a battery to protect them against desiccation and solid paraffins. Once power is restored, the instrument resumes the program at the same point in which it was interrupted. If it is a long power failure and the paraffin baths become solidified, the safety program will be activated. The instrument will then wait for the baths to be fully liquified before going ahead with the change to the paraffin baths. Emergency motions can be implemented through the battery, such as moving the basket up and down or station change (as long as the basket is not inside a solidified paraffin bath). The instrument is also equipped with an emergency stop button. It is possible to interrupt a program for reloading or advanced unloading of samples.

Alarms during the process

If the specimens remain inside a station for a longer time than the programmed time, e.g. due to a power failure, the display will show a message indicating the station number and the overtime spent in that station compared with the initially programmed time. The acoustic and visual alarms can easily be identified by the user. The keyboard can be locked by the user to avoid an inadvertent change of the process parameters during operation.

STP 120-3:
2 stainless steel baskets +
3 paraffin baths for processing up to 240 cassettes.

In anatomical pathology, tissue processing is a decisive factor. MYR has been offering for more than 30 years a broad range of histology equipment to perform the processing, the embedding, the sectioning and the staining of tissues. Many laboratories are already benefitting from the proven technology, the high reliability and the professional approach of a dedicated team. We meet your requirements. Because we are devoted to Histology.

Technical Data Spin Tissue Processor STP 120

Power requirements

Nominal voltage	100 - 120 V	220-240 V AC (± 10%)
Network's frequency	50/60 Hz	
Consumption	400 VA	
Fuses	115 V (2xT4A)	230 V (2xT2A)
Battery Nickel-Cadmium	12 V 600 mA	

Capacity

Reagent stations	
Number of vessels	10 (9 if 3 paraffin baths are used)
Volume per vessel	1,8 l
Paraffin stations	
Number	2 (optionally 3)
Volume	1,8 l
Nominal voltage	24 V AC
Nominal power per station	100 VA
Temperature setting range	45 - 70 °C in 1°C increments
Overtemperature release	75 °C (± 4 °C)
Cassette baskets	
Number of baskets	1 (optionally 2)
Basket capacity	120 cassettes (optionally 240)

Programming

Number of programs	10 (selectable)
Infiltration time per station	from 1 m to 90 h 59 m
Rotational agitation	selectable
Shaking	selectable
Centrifuging time	selectable
Program start delay	selectable without time limit

Dimensions

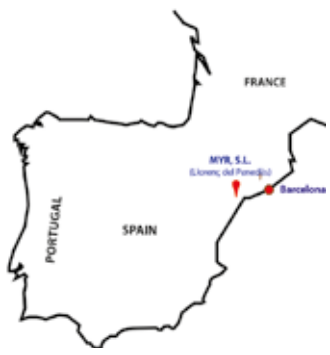
Diameter	850 mm
Height	500 - 700 mm
Diameter of the roller's circle	670 mm

Weight

Including packaging	130 kg
Net (fully equipped)	70 kg

Optional equipment

- Spiral support for a second cassette basket (double processing capacity)
- Additional basket
- Additional paraffin bath (necessary when operating the processor with the two baskets)
- Fume extraction system with active charcoal filter



Especialidades Médicas Myr S.L.

ISO 9001 / 13485 certified company

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Anexa 68, Histoprocesor automat vertical. MYR STM 120-3

Parametri solicitati	Parametri oferiti
Sistemul de ventilare a retortei, functional si dupa deschiderea retortei pentru a evita dispersarea de vapori de reactivi. -Controlat de microprocesor prin software multilingv prin intermediul unui ecran senzitiv (touch-screen) color rezistent la solventi; -Sistem de management al reagentilor care permite monitorizarea reagentilor in functie de numarul de casete procesate, cicluri de procesare sau zile de procesare. -Sistem de protectie pentru suprapresiune. -Sistem de protectie pentru supraincalzire. -Sistem de protectie pentru supraalimentare. -Minim 3 programe prestabilite din care unul scurt pentru biopsii si unul pentru procesare peste noapte. -Posibilitate de procesare la temperatura camerei sau de incalzire a reagentilor pentru procesare in domeniul 35-60 grade C -Minim 10 programe editabile cu minim 14 pasi in care se pot seta temperatura de procesare, timp de infiltrare, reactivi, presiune sau vacuum. -Conexiune USB care sa permita transferul programelor de procesare -Posibilitate de intarziere programabil cu pana la 7 zile; -Minim 3 bai de parafina cu temperatura setabila intre 50 si 70°C; -Capacitate bai parafina minim 3.5 litri -Minim 14 recipiente (11 reagenti de lucru, 2 reagenti de spalare, 1 colectare condens); -Capacitate recipiente minim 3.5 litri -Dotat cu 3 tavite de scurgere sub recipientele de reactivi si baile de parafina -Senzori de detectie de subumplere sau supraumplere vas de reactie; -Temperatura de minim 60 grade la reactivii de curatare pentru eficientizarea procesului -Posibilitate conectare la internet pentru supraveghere in timp real a functionarii si notificarea utilizatorului in caz de alarma -Cablu de alimentare tip Schuko -Alimentare la 220V, 50Hz -UPS pentru lucrul autonom al dispozitivului minim 15 min. -Garantie nu mai putin de 36 luni. -Instalare si instruire pentru utilizatori. -Efectuarea mentenanței la dispozitiv pe parcursul perioadei de garanție cu schimbare de piese la necesitate și în conformitate cu manualul producătorului.	Sistemul de ventilare a retortei, functional si dupa deschiderea retortei pentru a evita dispersarea de vapori de reactivi. Controlat de microprocesor prin software multilingv prin intermediul unui ecran LCD si butaone, rezistente la solventi; -Sistem de management al reagentilor care permite monitorizarea reagentilor in functie de numarul de casete procesate, cicluri de procesare sau zile de procesare. – NU -Sistem de protectie pentru suprapresiune. -Sistem de protectie pentru supraincalzire. -Sistem de protectie pentru supraalimentare. -10 programe setabile de catre operator conform necesitatilor, din care unul scurt pentru biopsii si unul pentru procesare peste noapte. -Posibilitate de procesare la temperatura camerei sau de incalzire a reagentilor pentru procesare in domeniul 45-70 grade C -10 programe editabile cu 14 pasi in care se pot seta temperatura de procesare, timp de infiltrare, agitare, centrifugare, intarziere start. -Conexiune USB care sa permita transferul programelor de procesare - NU -Posibilitate de intarziere programabil cu pana la 7 zile; - 3 bai de parafina cu temperatura setabila intre 45 si 70°C; -Capacitate bai parafina minim 1.8 litri -9 recipiente (7 reagenti de lucru, 2 reagenti de spalare); -Capacitate recipiente 1.8 litri -Nu este dotat cu 3 tavite de scurgere sub recipientele de reactivi si baile de parafina -Senzori de detectie de subumplere sau supraumplere vas de reactie; -Temperatura de minim 60 grade la reactivii de curatare pentru eficientizarea procesului - NU -Posibilitate conectare la internet pentru supraveghere in timp real a functionarii si notificarea utilizatorului in caz de alarma - NU -Cablu de alimentare tip Schuko -Alimentare la 220V, 50Hz -UPS pentru lucrul autonom al dispozitivului 15 min. -Garantie 36 luni. -Instalare si instruire pentru utilizatori. -Efectuarea mentenanței la dispozitiv pe parcursul perioadei de garanție cu schimbare de piese la necesitate și în conformitate cu manualul producătorului.

- Documente confirmative: Manual de service si manual de utilizare in conformitate cu LEGEA Nr. 102 cu privire la dispozitivele medicale din 09.06.2017, capitolul 4 Articolul 14. P. 3. Ghid rapid al utilizatorului (max. 4 pagini A4), in limba de stat-obligatoriu	Documente confirmative: Manual de service si manual de utilizare in conformitate cu LEGEA Nr. 102 cu privire la dispozitivele medicale din 09.06.2017, capitolul 4 Articolul 14. P. 3. Ghid rapid al utilizatorului (max. 4 pagini A4), in limba de stat-obligatoriu

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AUTHORIZATION TO MARK

This authorizes the application of the Certification Mark(s) shown below to the models described in the Product(s) Covered section when made in accordance with the conditions set forth in the Certification Agreement and Listing Report. This authorization also applies to multiple listee model(s) identified on the correlation page of the Listing Report.

This document is the property of Intertek Testing Services and is not transferable. The certification mark(s) may be applied only at the location of the Party Authorized To Apply Mark.

Applicant:	ESPECIALIDADES MEDICAS MYR, S.L.	**Manufacturer:**	ESPECIALIDADES MEDICAS MYR, S.L.
Address:	C/ Lleida, 17-23 Polígono Indl. L'Empalme E 43712 Llorenç del Penedès, Tarragona	**Address:**	C/ Lleida, 17-23 Polígono Indl. L'Empalme E 43712 Llorenç del Penedès, Tarragona
Country:	Spain	**Country:**	Spain
Contact:	Mr. Francisco Ruiz	**Contact:**	Mr. Francisco Ruiz
Phone:	(+34) 977 66 80 20	**Phone:**	(+34) 977 66 80 20
FAX:	(+34) 977 66 80 30	**FAX:**	(+34) 977 66 80 30
Email:	f.ruiz@myr.com.es	**Email:**	f.ruiz@myr.com.es

Party Authorized To Apply Mark: Same as Manufacturer
Report Issuing Office: Cortland, NY 13045

Control Number: 5000926 **Authorized by:**

for L. Matt Snyder, Certification Manager

C ETL LISTED US
Intertek

This document supersedes all previous Authorizations to Mark for the noted Report Number.

Intertek Testing Services NA Inc.
545 East Algonquin Road, Arlington Heights, IL 60005
Telephone 800-345-3851 or 847-439-5667 Fax 312-283-1672

Standard(s):	Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use - Part 1: General Requirements [UL 61010-1:2012 Ed.3+R:29Apr2016] Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use Part 1: General Requirements (R2017) [CSA C22.2#61010-1:2012 Ed.3]
Product:	Tissue preparation equipment
Brand Name:	**MYR**
Models:	EC 350-1, EC 350-2, EC 500-1, EC 500-1-TB, EC 500-2, EC 500-2-TB, EC 500-3, EC 500-3-TB, STP 120-followed by 1, 2, or 3, SS-30, SS-30H and M-240

LAO

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

AENOR *has issued an IQNet recognized certificate that the organization:*

ESPECIALIDADES MEDICAS MYR, S.L.

CL LLEIDA, 17-23.
43712 - LLORENÇ DEL PENEDES
(TARRAGONA)

has implemented and maintains a

Quality Management System

for the following scope:

Design, development and production of machines for pre-treatment before analysis and diagnosis of all types of tissues: human, animal and vegetable.

which fulfills the requirements of the following standard

ISO 9001:2015

First issued on: ***2014-01-24*** *Last issued:* ***2020-03-13*** *Validity date:* ***2023-03-13***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: ***ES-0031/2014***

Alex Stoichitoiu
President of IQNet

Rafael GARCÍA MEIRO
Chief Executive Officer

AENOR

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FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
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NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
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Original Electronic Certificate

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

AENOR *has issued an IQNet recognized certificate that the organization:*

ESPECIALIDADES MEDICAS MYR, S.L.

CL LLEIDA, 17-23.
43712 - LLORENÇ DEL PENEDES
(TARRAGONA)

has implemented and maintains a

Medical devices – Quality Management Systems

for the following scope:

Design, development and production of machines for preparation of all types of tissues for in vitro diagnostic.

which fulfills the requirements of the following standard

ISO 13485:2016

First issued on: ***2014-03-28*** *Last issued:* ***2020-03-28*** *Validity date:* ***2023-03-28***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: ***ES-GS-0002/2014***

Alex Stoichitoiu
President of IQNet

Rafael GARCÍA MEIRO
Chief Executive Officer

AENOR

IQNet Partners*:
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CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

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