

Anexa 1 Lot 1 Sistem automat de colorare, lame port- obiect

SS-30, Myr, Spania

Parametri solicitati	Parametri oferiti
Sistem automat de colorare, lame port- obiect Descriere Dispozitiv pentru colorarea automată a lamelor pentru hematologie, citologie, histologie, bacteriologie, s.a. Parametru Specificația Caracteristici sistem Procesare simultană ≥ 5 stative Stații de procesare ≥ 20 Stații incarcare ≥ 5 Stații de descarcare ≥ 5 Stații de spalare ≥ 5 Capacitate stativ ≥ 30 lame Cuvetă spălare/ colorare ≥ 400 ml. Memorie ≥ 20 programe Capacitate program ≥ 50 pași Posibilitatea de a programa sistemul de agitare Posibilitatea de a programa sistemul de agitare pentru fiecare stație în parte . da Program special pentru statii de spalare da Moduri de programare ≥ 4 Parametri configurabili ≥ 3 (număr,viteza,amplituda) Timp de imersie 1 sec -59 min, pasul ≥ 59 sec Memorie reagenti Pre- programati ≥ 30 Definiți de utilizator ≥ 20 Real – time display pentru protocoalele executate da Ecran tactil ≥ 7 inch Calculator încorporat da Funcție de drenare reagent da Filtru pentru purificare aer cu carbune activ da Conectare la sistemul de apă Presiunea ≤ 4 bar Temperatura ≤ 30 °C Standard conectare $\frac{3}{4}$” Sistem dublu de protecție scurgere da Sistem canalizare Drenaj prin gravitație da Caracteristici, alimentare Baterie UPS da Autonomie acumulator ≥ 2 ore Accesorii Vas pentru reagenți ≥ 20 buc. Vas pentru apă ≥ 5 buc. Capac pentru vas ≥ 25 buc. Stativ pentru lame (capacitate 30 lame) ≥ 3 buc. Suport pentru stativ cu lame ≥ 3 buc.	Sistem automat de colorare, lame port- obiect Descriere Dispozitiv pentru colorarea automată a lamelor pentru hematologie, citologie, histologie, bacteriologie, s.a. Parametru Specificația Caracteristici sistem Procesare simultană 5 stative Stații de procesare 19 Stații incarcare 2 Stații de descarcare 3 Stații de spalare 3 Capacitate stativ 30 lame Cuvetă spălare/ colorare 300 ml Memorie 20 programe Capacitate program 50 pași Posibilitatea de a programa sistemul de agitare Posibilitatea de a programa sistemul de agitare pentru fiecare stație în parte . da Program special pentru statii de spalare da Moduri de programare 4 Parametri configurabili 3 (număr,viteza,amplituda) Timp de imersie 1 sec -59 min, pasul ≥ 59 sec Memorie reagenti Pre- programati 32 Definiți de utilizator 20 Real – time display pentru protocoalele executate da Ecran tactil 5 inch, butoane pentru programare Calculator încorporat da Funcție de drenare reagent da Filtru pentru purificare aer cu carbune activ da Conectare la sistemul de apă Presiunea ≤ 4 bar Temperatura ≤ 30 °C Standard conectare $\frac{3}{4}$” Sistem dublu de protecție scurgere da Sistem canalizare Drenaj prin gravitație da Caracteristici, alimentare Baterie UPS da Autonomie acumulator ≥ 2 ore Accesorii Vas pentru reagenți 20 buc. Vas pentru apă 5 buc. Capac pentru vas 25 buc. Stativ pentru lame (capacitate 30 lame) 3 buc. Suport pentru stativ cu lame 3 buc.

Tub pentru conectare la sistemul de apă ≥ 1 (~1,5 m) Tub pentru conectare la sistemul de canalizare ≥ 1 (~3 m) Filtru pentru purificare aer cu carbune activ ≥ 1 buc. Reagent pentru 1000 de probe da	Tub pentru conectare la sistemul de apă 1 (~1,5 m) Tub pentru conectare la sistemul de canalizare 1(~3 m) Filtru pentru purificare aer cu carbune activ 1 buc. Reagent pentru 1000 de probe da
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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

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CERTIFICATE

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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**

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Registration Number: ES-GS-0002/2014



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Myr

AUTOMATED
SLIDE STAINER

SS-30

Flexible and versatile design for
optimized staining results

Devoted to Histology 



AUTOMATED SLIDE STAINER

SS-30

FOR ROUTINE AND SPECIAL STAINING PROTOCOLS
IN HISTOLOGY AND CYTOLOGY LABS

Flexible, optimized and user-friendly

MULTISTAINING CAPABILITY

More staining flexibility allowing simultaneous and automatic staining of various 30-slide racks with identical or different staining protocols. Continuous loading to maximize efficiency and productivity in labs.

Up to 5 slide racks can be run simultaneously depending on protocols, load frequency and instrument configuration, enabling up to 150 slides to be stained simultaneously. The instrument calculates the most efficient route for each rack/protocol.

FLEXIBLE STAINING

The agitation system can be individually programmed for each station: it is available in 4 different preset dip modes with 3 configurable parameters: number, speed and amplitude of the dips. A special programming for the washing stations is also available.

Several adaptors are available for the most popular coverslipper racks in the market.

COMPACT FOOTPRINT

Ideal for labs with shallow benches to optimize valuable space. Smartly designed to occupy less space without compromising slide staining productivity.

REAL-TIME DISPLAY

SS-30 displays in real time the status of each staining protocol. It can store up to 20 programmed protocols in memory with 50 steps each maximum as well as up to 52 reagents (32 pre-programmed).

The drain function minimizes the reagent carryover and helps reducing reagent consumption to optimize costs.

DEDICATED SOFTWARE

SS-30 stainer is supplied with a PC dedicated software that offers the option to define protocols and modify the list of saved reagents from the convenience of a PC.

It has also reporting capabilities through a USB plug to acquire data, displaying real status of the running protocols and managing reports and errors.



USER AND SPECIMEN SAFETY

Lab-friendly integrated filtration system equipped with a charcoal filter and individual lids for the reagent stations to avoid evaporation of reagents. Optional adaptor for the laboratory general extraction system.

Back-up battery with 2h autonomy to finish the staining protocols in case of power failure. External 12V power supply.

The transparent hood is equipped with two hinged doors (loading/unloading stations) to reduce the exposure to reagents.

Water overflowing in the stainer is secured thanks to an innovative two water level sensors system.

The Reagent Management System (RMS) keeps track of reagent usage and ensures an optimal staining quality (available only in version SS-30H).



SPECIFICATIONS

Specimens	Histological and/or cytological
Staining capacity	Up to 5 racks simultaneously
Slide rack capacity	30 slides
Number of programs	Up to 20 programs with max. 50 steps each
Immersion time	From 1 s to 59 m 59 s per step
Agitation system	Independently programmable for each station
Selectable parameters	Number, speed and amplitude of dips
Drain function	Minimizes reagent carryover
Total stations	20 vessels with individual lid
Reagent stations	Up to 19
Reagent stations capacity	300 ml
Water stations	Up to 3
Load stations	Up to 2
Unloading stations	Up to 3 (2 if drying station is available)
Drying station	1 (available only in SS-30H)
Drying station temperature	30 to 70° C
Fume extraction system	Charcoal filter
Power requirements	
SS-30	100-240VAC 50-60Hz 0,17A
SS-30H	100-240VAC 50-60Hz 0,76A
Backup battery capacity	2 h
Dimensions (l x w x h)	1.200 x 440 x 368 mm
Weight	55 kg

ORDERING INFORMATION

SS-30	Automated slide stainer	100-240v / 50-60 Hz
SS-30H	Automated slide stainer with drying station	100-240v / 50-60 Hz

OPTIONAL ACCESSORIES

SS30-059	Adapter for THERMO-MICROM rack (30 slides)
SS30-200	Load station LEICA racks
SS30-200B	Lid for load station LEICA rack
SS30-201	Adapter for LEICA plastic rack (30 slides)
SS30-201B	Adapter for LEICA metal rack (30 slides)
SS30-202	Adapter for SAKURA rack (20 slides)
SS30-204	Adapter for MEDITE rack (20 slides)
SS30-205	Adapter for MEDITE rack (30 slides)
SS30-210	Megaslides adapter

Especialidades Médicas Myr S.L

ISO 9001 / 13485 certified company

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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 products / *Declaramos bajo nuestra responsabilidad que los productos*

Slide Stainers SS-30 and SS-30H / *Teñidores de Tejidos SS-30 y SS-30H*

meet all the requirements of the following European Directives that are applicable
cumplen 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 products are designed and manufactured according to the relevant parts of the following International Standards
Los productos están diseñados y fabricados de acuerdo con las partes relevantes de los siguientes estándares

IEC 61010-1: 2010	IEC 61010-2-010: 2014
IEC 61010-2-101: 2002	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, 19/06/2019

Francisco Ruiz Robles
Managing Director / *Director General*