

Anexa 1. Dispozitiv pentru coloratia frotiului, metoda de coloratie Papanicolau

MYR, model SS-30H

Parametri solicitati	Parametri oferiti
<p>Dispozitiv pentru colorarea frotiului, metoda de colorație Papanicolau</p> <p>Descriere Acest dispozitiv medical este destinat colorării automate a frotiurilor de sânge, a preparatelor microbiologice, citologice și a altor preparate pe lamele de sticlă conform unui program prestabilit.</p> <p>Parametrul Specificația</p> <p>Cantitatea stațiilor combinate, buc. 10</p> <p>Stații de uscare, buc. 2</p> <p>Numărul de stații de spălare cu apă curentă, buc. 1</p> <p>Numărul maxim de ochelari într-un treiped, buc. 25</p> <p>Temperatura de uscare 30 - 50 °C, ± 5</p> <p>Ventilarea camerei de lucru da</p> <p>Display LED, LCD</p> <p>Numărul de metode de colorare incluse ≥ 10</p> <p>"Număr programabil de tehnici de colorare a preparatelor " ≤ 30</p> <p>"Numărul de operări tehnologice din programul de colorare " ≤ 29</p> <p>"Numărul fluidelor de proces " ≤ 50</p> <p>Alimentare 220 V, 50 Hz</p>	<p>Dispozitiv pentru colorarea frotiului, metoda de colorație Papanicolau</p> <p>Descriere Acest dispozitiv medical este destinat colorării automate a frotiurilor de sânge, a preparatelor microbiologice, citologice și a altor preparate pe lamele de sticlă conform unui program prestabilit.</p> <p>Parametrul Specificația</p> <p>Cantitatea stațiilor combinate, buc. 20</p> <p>Stații de uscare, buc. 1</p> <p>Numărul de stații de spălare cu apă curentă, buc. Pina la 3, numar selectabil de operator</p> <p>Numărul maxim de lame(sliede-uri) într-un support(rack), buc. 30</p> <p>Temperatura de uscare 30 - 70 °C, ± 5</p> <p>Ventilarea camerei de lucru da, echipata cu filtru de carbune</p> <p>Display LCD</p> <p>Numărul de metode de colorare incluse 10</p> <p>"Număr programabil de tehnici de colorare a preparatelor " 20, fiecare cu pina la 50 pasi</p> <p>"Numărul de operări tehnologice(pasi/etape) din programul de colorare " pina la 50</p> <p>"Numărul fluidelor de proces " 52, din care 32 deja preprogramate</p> <p>Alimentare 220 V, 50 Hz</p>

Anexa 12, Dispozitiv automat pentru colorarea frotiurilor citologice. MYR SS-30

Parametri solicitati	Parametri oferiti
<p>Dispozitiv automat pentru colorarea frotiurilor citologice</p> <p>Descriere Dispozitiv pentru colorarea automata a lamelor pentru hematologie, citologie, histologie, bacteriologie, s.a.</p> <p>Parametru Specificația</p> <p>Caracteristici sistem procesare simultana ≥ 5 stativ</p> <p>statii de procesare, total ≥ 20</p> <p>statii de incarcare ≤ 2</p> <p>statii de descarcare ≤ 3</p> <p>statii de spalare ≤ 3</p> <p>capacitate stativ ≥ 30 lame</p> <p>volum reagent / statie ≥ 300 ml</p> <p>memorie ≥ 20 programe</p> <p>capacitate program ≥ 50 pasi</p> <p>posibilitatea de a programa sistemul de agitare pentru fiecare statie in parte</p> <p>posibilitatea de a programa sistemul de agitare pentru fiecare statie in parte da</p> <p>program special pentru statii de spalare da</p> <p>moduri de programare ≥ 4</p> <p>parametri configurabili ≥ 3 (numar, viteza, amplituda)</p> <p>timp de imersie 1 sec - 59 min, pasul ≥ 59 sec</p> <p>memorie reagenti pre-programati ≥ 32</p> <p>definiti de utilizator ≥ 20</p> <p>real-time display pentru protocoalele executate da</p> <p>functie de drenare reagent da</p> <p>interfata USB pentru transmiterea datelor spre calculator da</p> <p>filtru pentru purificare aer cu carbon activat da</p> <p>conectare la sistem de apa presiunea ≤ 4 bar</p> <p>temperatura ≤ 30 °C</p> <p>standard conectare $\frac{3}{4}$"</p> <p>sistem dublu de protectie scurgere da</p> <p>sistem canalizare drenaj prin gravitatie da</p> <p>diametru teava ≤ 20 mm</p> <p>Caracteristici alimentare Acumulator LI-ion da</p> <p>Autonomie acumulator ≥ 2 ore</p> <p>Alimentare prin bloc de alimentare extern Da</p> <p>Acesorii</p> <p>Dispozitivul sa fie livrat impreuna cu toate accesoriile necesare pentru punerea in functiune al dispozitivului</p>	<p>Dispozitiv automat pentru colorarea frotiurilor citologice</p> <p>Descriere Dispozitiv pentru colorarea automata a lamelor pentru hematologie, citologie, histologie, bacteriologie, s.a.</p> <p>Parametru Specificația</p> <p>Caracteristici sistem procesare simultana 5 stativ</p> <p>statii de procesare, total 20</p> <p>statii de incarcare 2</p> <p>statii de descarcare 3</p> <p>statii de spalare 3</p> <p>capacitate stativ 30 lame</p> <p>volum reagent / statie 300 ml</p> <p>memorie 20 programe</p> <p>capacitate program 50 pasi</p> <p>posibilitatea de a programa sistemul de agitare pentru fiecare statie in parte</p> <p>posibilitatea de a programa sistemul de agitare pentru fiecare statie in parte da</p> <p>program special pentru statii de spalare da</p> <p>moduri de programare 4</p> <p>parametri configurabili 3 (numar, viteza, amplituda)</p> <p>timp de imersie setabil de la 1 sec – pina la 59 min 59 sec, pasul selectabil in sec</p> <p>memorie reagenti pre-programati 32</p> <p>definiti de utilizator 20</p> <p>real-time display pentru protocoalele executate da</p> <p>functie de drenare reagent da</p> <p>interfata USB pentru transmiterea datelor spre calculator da</p> <p>filtru pentru purificare aer cu carbon activat da</p> <p>conectare la sistem de apa presiunea 4 bar</p> <p>temperatura ≤ 30 °C</p> <p>standard conectare $\frac{3}{4}$"</p> <p>sistem dublu de protectie scurgere da</p> <p>sistem canalizare drenaj prin gravitatie da</p> <p>diametru teava 20 mm</p> <p>Caracteristici alimentare Acumulator LI-ion da</p> <p>Autonomie acumulator 2 ore</p> <p>Alimentare prin bloc de alimentare extern Da</p> <p>Acesorii</p> <p>Dispozitivul va fi livrat impreuna cu toate accesoriile necesare pentru punerea in functiune al dispozitivului</p>

<p>vas pentru reagenti ≥ 20 buc</p> <p>vas pentru apa ≥ 3 buc</p> <p>capac pentru vas ≥ 23 buc</p> <p>stative pentru lame (capacitatea 30 lame) ≥ 3 buc</p> <p>suport pentru stativ cu lame ≥ 3 buc</p> <p>tub pentru conectarea la sistemul de apa ≥ 1 (~1,5 metri)</p> <p>tub pentru conectarea la sistemul de canalizare ≥ 1 (~3 metri)</p> <p>filtru pentru purificare aer cu carbon activat ≥ 1 buc</p> <p>Cablu USB pentru conectarea la calculator ≥ 1 buc</p> <p>bloc de alimentare ≥ 1 buc</p> <p>calculator pentru programare ≥ 1 buc</p>	<p>vas pentru reagenti total 20 buc, dedicate reagenti 19</p> <p>vas pentru apa 3 buc</p> <p>capac pentru vas 23 buc</p> <p>stative pentru lame (capacitatea 30 lame) 3 buc</p> <p>suport pentru stativ cu lame 3 buc</p> <p>tub pentru conectarea la sistemul de apa 1 (~1,5 metri)</p> <p>tub pentru conectarea la sistemul de canalizare 1 (~3 metri)</p> <p>filtru pentru purificare aer cu carbon activat 1 buc</p> <p>Cablu USB pentru conectarea la calculator 1 buc</p> <p>bloc de alimentare 1 buc</p> <p>calculator pentru programare 1 buc</p>
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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*

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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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President of IQNet*

*Rafael GARCÍA MEIRO
Chief Executive Officer*

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SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

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

Control Number: 5000926

Authorized by: _____

(Handwritten Signature)
for L. Matt Snyder, Certification Manager



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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



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*

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

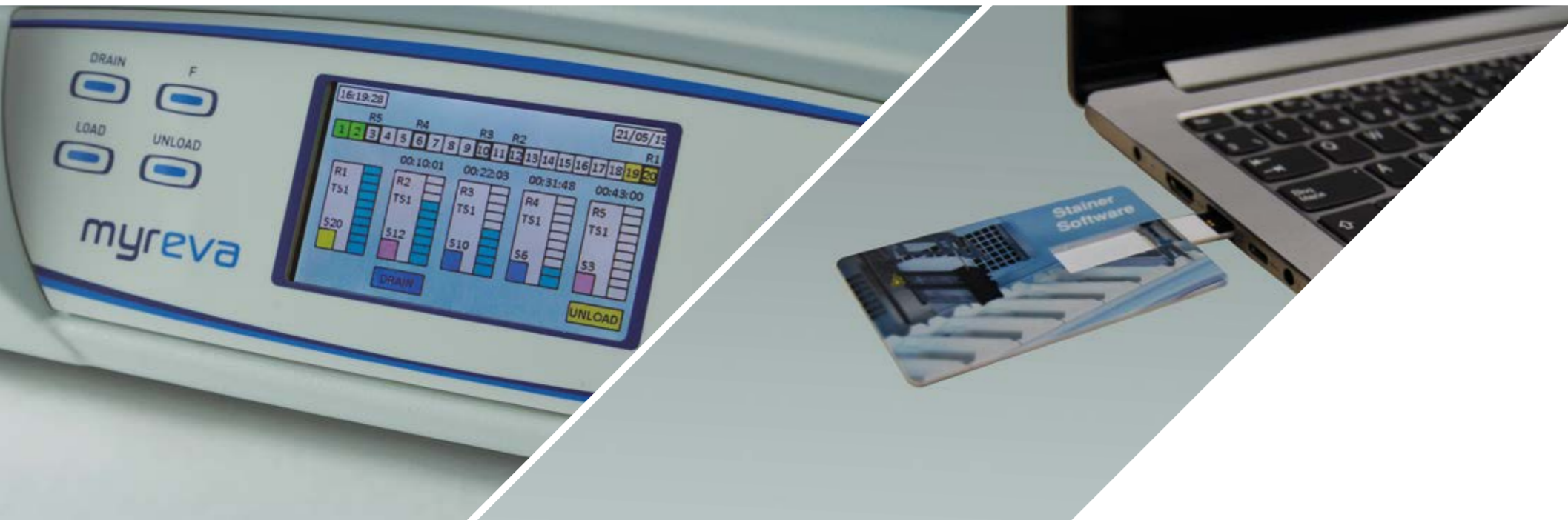
SS-30 displays in real time the status of each staining protocol. It can store up to 20 programmed protocols in memory with 50 steps each maximum as well as up to 52 reagents (32 pre-programmed).

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

Lleida, 17-23

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Tel. +34 977 66 8020

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esp.medicas@myr.com.es

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Local Distributor. Contact information.

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Email: f.ruiz@myr.com.es	Email: f.ruiz@myr.com.es

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Myr

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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

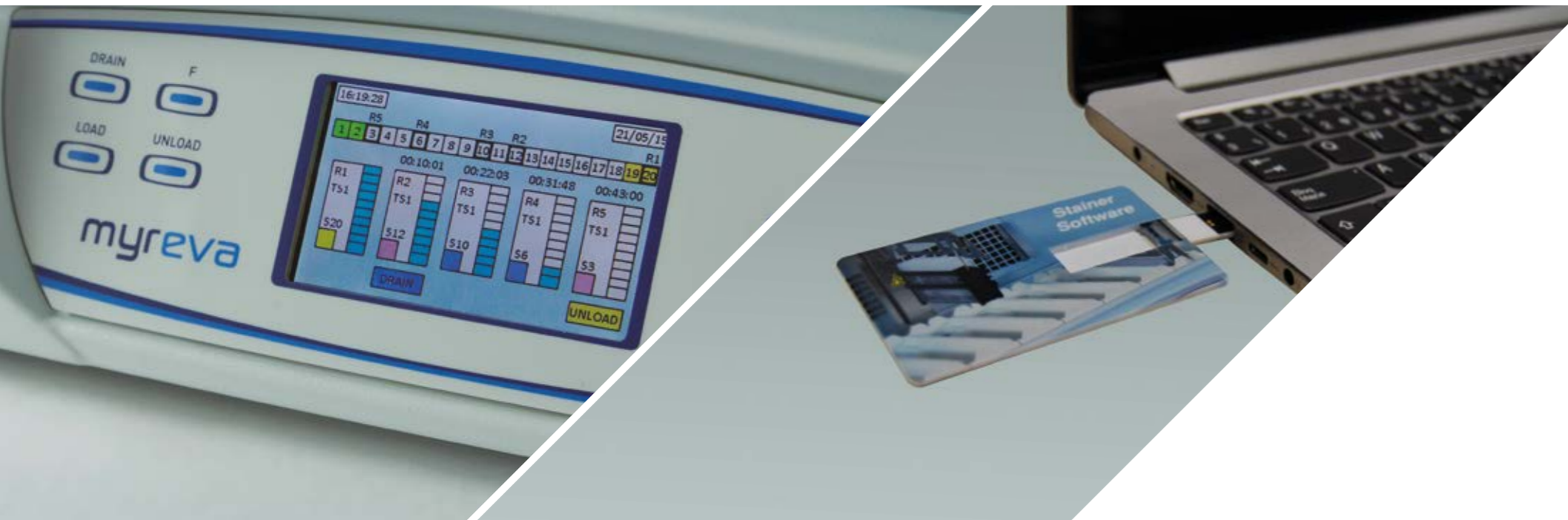
SS-30 displays in real time the status of each staining protocol. It can store up to 20 programmed protocols in memory with 50 steps each maximum as well as up to 52 reagents (32 pre-programmed).

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

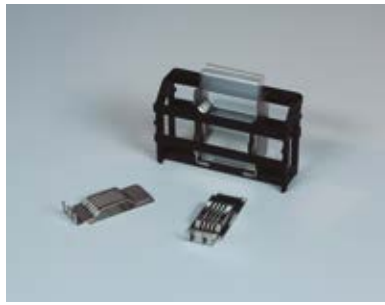
Lab-friendly integrated filtration system equipped with a charcoal filter and individual lids for the reagent stations to avoid evaporation of reagents. Optional adaptor for the laboratory general extraction system.

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
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Drain function	Minimizes reagent carryover
Total stations	20 vessels with individual lid
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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

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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 Mèdicas Myr S.L

ISO 9001 / 13485 certified company

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