Medical Printex®

Tracking System Sterilization for CSSD

Documentation labels for the sterilization tracking

Made in Italy

Printex documentation labels for CSSD
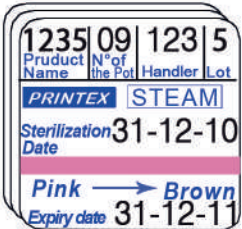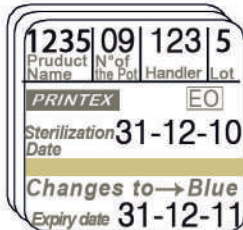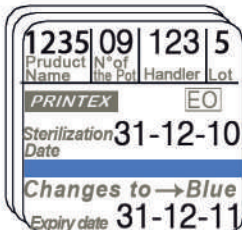
Printex labels for CSSD documentation are made in double adhesive support and with Type 1 process indicators according to EN ISO 11140-1.We produce labels with indicator for STEAM, EO and PLASMA sterilization.The tracking system is necessary to share details about the sterilization cysle and for having data on the record sheet of the hospital or of the patient.

As follows,lots of information can be printed on the documentation labels thanks to our Printex Handlabellers:

• Sterilization date
• Expiry date
• Operator
• Sterilization cycle number
• Batch/Lot number
• Product number
• Sterilizer code

To have a complete track of the sterilization cycle we recommend to stick on the pouch at least two labels with the same content.After opening the sterile pack in the operation room one label can be peeled off and stuck on a record sheet of the patient. This system allows to have a complete tracking of the instruments in the sterilization department. Our labels can be also personalized in different colours, maybe related to the different hospital department.

Following details about our labels with indicator:

Sterilization process	Indicator colour (without penetration)	Indicator colour (after penetration)
Steam It is the process of destroying all microorganisms and their pathogenic products.It is accomplished by heat (wet steam under pressure at 120°C for at east 45 minutes, or dry heat at 160-180°C for 3 hours	*Pink* → 1235 09 123 5 / Pruduct Name / N°of the Pot / Handler / Lot / PRINTEX STEAM / Sterilization Date 31-12-10 / Pink → Brown / Expiry date 31-12-11	*Brown* 1235 09 123 5 / Pruduct Name / N°of the Pot / Handler / Lot / PRINTEX STEAM / Sterilization Date 31-12-10 / Pink → Brown / Expiry date 31-12-11
Ethylene Oxide (EO) It is a gas used in manufacturing organic compounds and as a fumigant, fungicide, and sterilizing agent.It is highly irritating to the eyes and mucous membranes	*Changes to* → 1235 09 123 5 / Pruduct Name / N°of the Pot / Handler / Lot / PRINTEX EO / Sterilization Date 31-12-10 / Changes to → Blue / Expiry date 31-12-11	*Blue* 1235 09 123 5 / Pruduct Name / N°of the Pot / Handler / Lot / PRINTEX EO / Sterilization Date 31-12-10 / Changes to → Blue / Expiry date 31-12-11
Hydrogen peroxide (VH2O2) It is a disinfectant and sterilizing agent without antiseptic properties because it is rapidly inactivated by enzymes in the skin. However, the frothing that occurs is beneficial since it loosens debris in wounds.	*Pink* → 1235 09 123 5 / Pruduct Name / N°of the Pot / Handler / Lot / PLASMA VH2O2 / PRINTEX Sterilization Date 31-12-10 / Pink → Yellow / Expiry date 31-12-11	*Yellow* 1235 09 123 5 / Pruduct Name / N°of the Pot / Handler / Lot / PLASMA VH2O2 / PRINTEX Sterilization Date 31-12-10 / Pink → Yellow / Expiry date 31-12-11

Our labels can be realized and produced according to your needs

Printex® Labeller
Mod.Medical A2/20
2 Print Lines

Pink → Brown **Indicators**

26x16mm

| 30.12.15 | | 890 |
| 30.12.18 | | 130 |

LOT

Original Ink-rolls

For Labellers Printex 1-2 Print Lines

Pink → Brown **Indicators**

| 31-SET-12 | 890 LOT |
| 31-DIC-12 | 130 |

| 31.09.12 Date Sterilization | Steam Pink→Brown |
| Expiry Date 31.12.12 | |
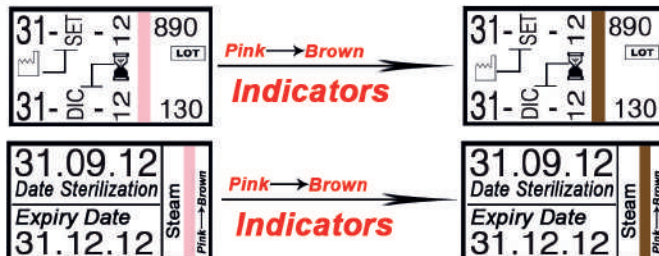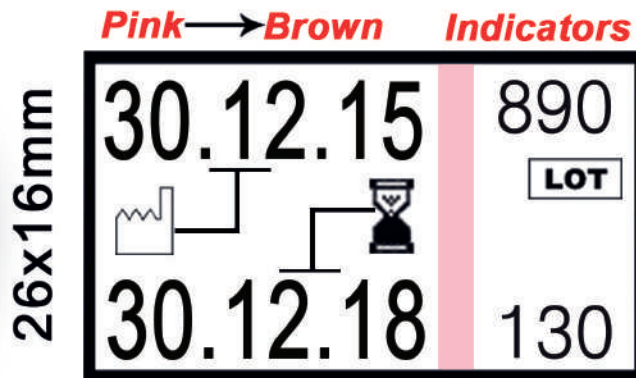
Our PRINTEX MEDICAL LABELLERS V2/20 and A2/20
2 print lines, can print 10+10 DIGITS with Numerical,
Alphabetic or alphanumerical codes.

Printex® Mod.Medical V2/20
2 Print Lines

26x16mm Label Size

26x16mm Rett
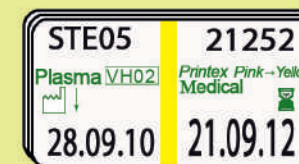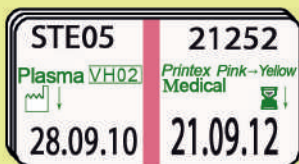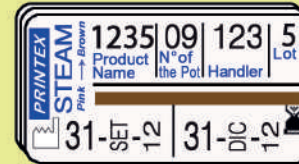
Mod.A
DIC Date Load N°
31 13 1200
STERILIZED
Indefinite shelf Life
Unless Damaged or Opened

26x16mm Rett

Mod.C
DIC Date Load N°
31 13 1200
STERILIZED
Indefinite shelf Life
Unless Damaged or Opened

26x16mm W

Mod.B
DIC LOAD NUMBER
31 13 1200
STERILE
Unless Damaged or Open Or Wet
26-DEC2014

26x16mm W

Mod.D
DIC LOAD NUMBER
31 13 1200
STERILE
Unless Damaged or Open Or Wet
26-DEC2014

Printex® Mod.Medical 3/2/14
Labeller 37x19mm Label Size
2 Print Lines

Mod.A
Red→Brown STEAM
DATE STERILIZATION
25-12-2012
Expiry date
25-12-2013

Mod.B
PRINTEX STEAM Pink→Brown
1235 Product Name | 09 N°of the Pot | 123 Handler | 5 Lot
31-SET-12 | 31-DIC-12

Mod.C
STE05 | 21252
STEAM BROWN BRAUN }=Ster. | MARRONE MARRON }=Ster. 0039 06 9770590 STEAM
Printex Italy
28.09.10 | 21.09.12

Mod.D
STE05 | 21252
Plasma VH02 | Printex Pink→Yellow Medical
28.09.10 | 21.09.12
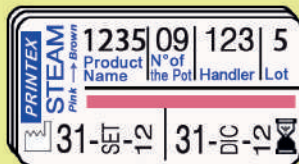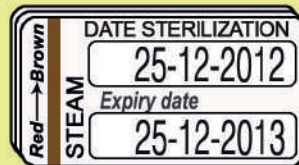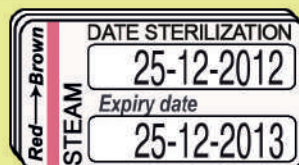
Other Labels

Labels with process indicator
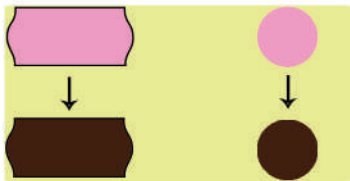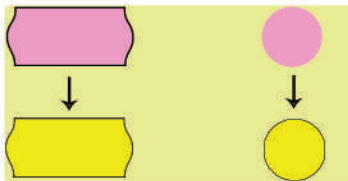
STEAM	VH2O2	EO
A 26X12mm **B** Diam.12mm	**A** 26X12mm **B** Diam.12mm	**A** 26X12mm **B** Diam.12mm
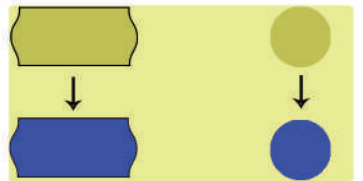
LABELS FOR "MONARCH" SYSTEM SIZE 25X31mm

STEAM
Dampf STEAM Vapeur
Pink/Rosa/Rose → Brown/Braun/Brun

VH2O2
PLASMA VH2O2
Pink/Rosa/Rose → Yellow/Gelb/Jaune

EO
EO
Changes To → Blau/Blue/Bleu
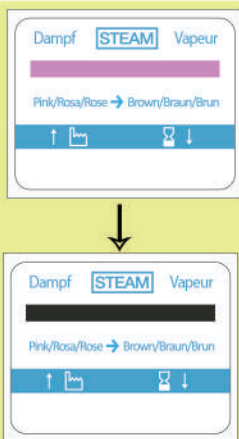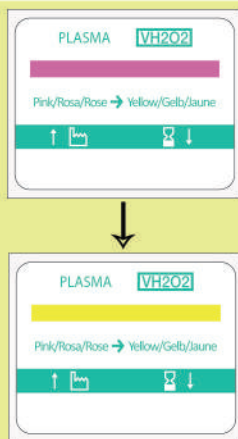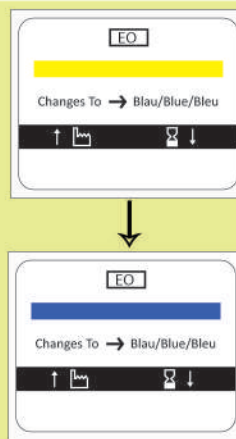
Original Ink-rolls
Ink rolls for Monarch Labeller

Printex ITALY
Farbrolle / ink roll
REF TAMP/MK
Lot-No 30 1401 Exp. 01-2018
For MONARK

Examples of PERSONALIZED labels

29x28mm WITH INDICATOR 11+11+11 digits

| 1235 | 09 | 123 | 5 |
品名 锅号 操作者 锅次
PRINTEX STEAM
灭菌日期: 31-12-10
Pink → Brown
失效日期: 31-12-11

| 1235 | 09 | 123 | 5 |
Sterilisation Numero / N° Produit / N° Opérateur / Lot
PRINTEX STEAM
Date de Sterilisation 31-12-10
Rose → Brun
Date d'expiration 31-12-11

| AM35 | 09 | 123 | 5 |
Pruduct Name / N°of the Pot / Handler / Lot
PRINTEX STEAM
Sterilization Date 31-12-10
Pink → Brown
Expiry date 31-12-11
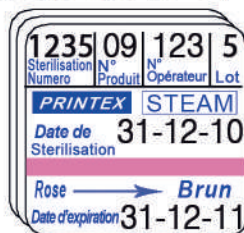
29x28mm WITHOUT INDICATOR 11+11+11 digits

| 1235 09 | 25 |
N° Sterilisation | Autoc.
Preremption | Agent
31-12-10 | 56
Cycle/Lot | Produit
12-11 | 2558A
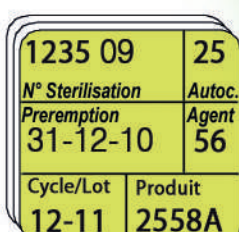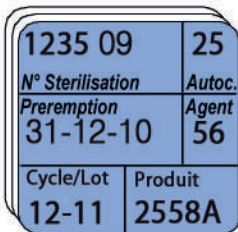
32x28mm WITH INDICATOR 14+14+14 digits

AP / 150 / 2013
MATERIAL
LOT
AP / 150 / 2013
Pink → Brown
EXPIRY DATE
31-12-11

JAN 30-13 DIC 30 2013
STEAM CHANGES - BROWN
LOT-500/2013-3
AMERICAN Medical Items
AM100-BA1200VA

EM 01 05 14/9
STEAM pink→brown
2013-03-27-AM
2015-03-27-AM

Each band can be numerical or Alphanumerical

We can CUSTOMIZE labels as you need
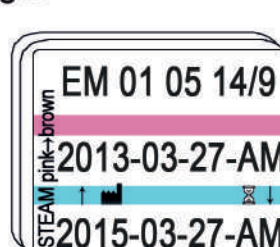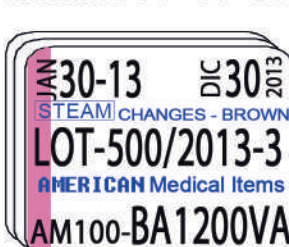
Original Ink-rolls
For Labellers Printex 3 Print Lines

HOW TO USE

1. Before each cycle fill the cycle form sheet. Then Insert the roll into the labeller and set the Labeller by entering the batch number,packing,expiry date,operator,autoclave, code etc..After print the labels. The first label must be put onto the cycle form sheet.

2. You must print the same number of labels as bags have to put into the autoclave.Stick the labels directly onto the paper side of the bag.

3.Then put the bags into the autoclave and start the sterilization cycle. When the cycle has finished, remove the bags and place them in the appropriate compartments.

4.Remove the previously label and stick it onto the patient's form.

5. At this stage the trucking in completed. This simple procedure assures us the trucking of the instruments at any time, It provides you with sterilization date of each and every instruments and the name of the patient on whom each of the sterile instruments was used. It also enables checking of the sterility expiry date.

Batch number   Operator

Product name code

N° of Lot

1235 | 09 | 123 | 5
Pruduct Name | N°of the Pot | Handler | Lot

PRINTEX   **STEAM**

Sterilization date

Sterilization Date 31-12-10

Indicator

Pink ⟶ **Brown**

Expiry date

Expiry date 31-12-11

Our labels have Double Adhesive and Class I process indicator
According to EN ISO 11140-1

WHY TO HAVE A TRACEABILITY DOCUMENTATION

The MDD(European Medical Devices Directive) requires for reprocessing of medical devices to use appropriate validated procedures and to document the results of rhe validation process and routine monitoring.

According to EN ISO 13485 is required monitoring and documentation for all relevant sterilization process parameters.

WHY DOCUMENTATION IS NECESSARY

Not compling with the rules of precaution involves significant infection's risks punishable by law. In this case the doctor will have to compensate the damage caused to the injured part and He will have to answer for such negligence before the law in court.

Do not risk! The sterilization instruments allows you to have the traceability of the same. Thanks to this mechanism, it is possible to know the type of cycle used, the batch, the operator, the sterilization date and expiry date.

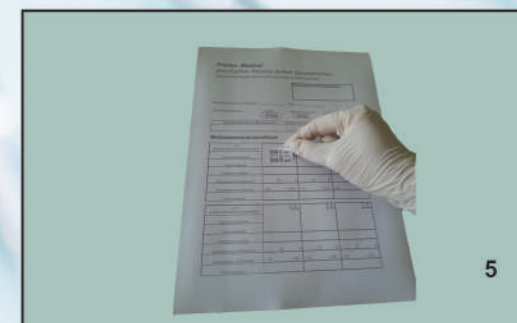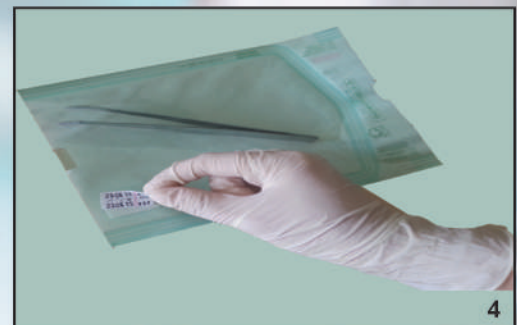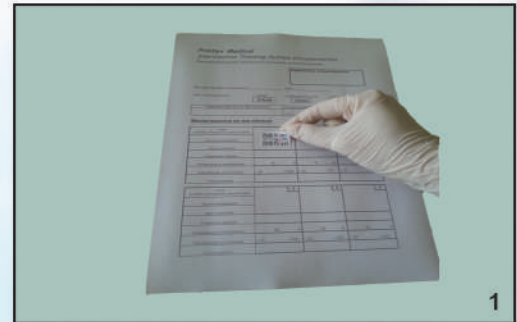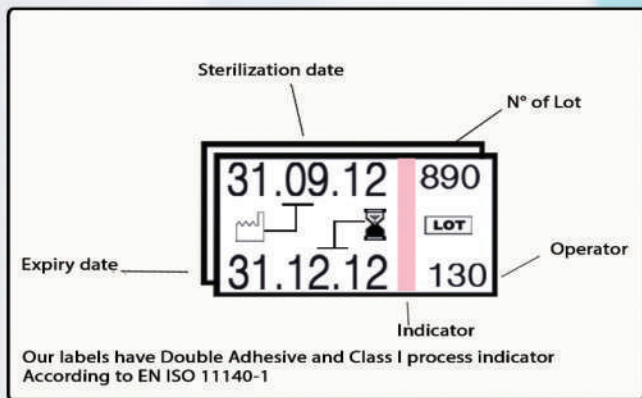*Respect your patients and
your medical practice*

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Sterilization date

N° of Lot

31.09.12 890

Expiry date

31.12.12 130

Operator

Indicator

Our labels have Double Adhesive and Class I process indicator According to EN ISO 11140-1

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Respect your patients and
your medical practice

1

2

3

4

5

D-Trace

The digital system to print documentation labels

D-Trace system has been realized to print **documentation label for CSSD** and give the possibility to have a **full identification and traceabilty of your instruments** in a sure and fast way.

It has been thought to be handy and easy to use by each operator. Thanks to this system used with our thermal transfer labels with chemical Indicator Type 1 (steam,eo,plasma) you can be sure that each procedure in the sterilization department has been successful.

Printing your documentation labels has never been easier!

70x35

LOT A000001

General Rome Hospital

Ortopedics   30/05/2018

Femur Kit   30/05/2021

Lucas Martin

Cycle No: 142

121°C- Steam

EN ISO 11140-1:2014   Type 1

STEAM   Pink → Brown   Printex

The QR code printed on each label will save your time avoiding to type each parameter using the keyboard. Once you scan the QR code using Printex Scanner reader, automatically the software will fill the gaps with the parameters of the QR code of your old label.

Minimum Requirements:

-500 MHZ PROCESSOR
- 512 MB RAM

Compatible with:

- MICROSOFT WINDOWS XP/VISTA/7/8 A 32/64 BIT

The D-Trace software is fully licenced and manufactured by Printex.

Made in Italy
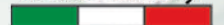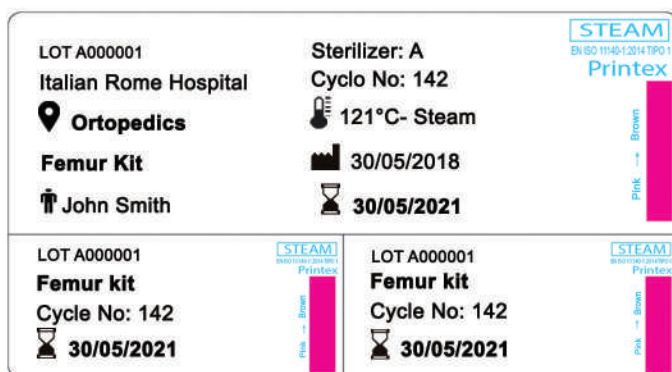
D-Trace

D-Trace software is fully licenced and manufactured by Printex. Thanks to it you can print all details required by CSSD, like **LOT, item, operator, sterilization date, expiry date, cycle type and cycle No .**

Printex studied for you a digital solution to track your instrument during their cycle in the sterilization department.

The Printex D-Trace System includes both our self-made software and our thermal transfer printer: Easy to install,fast,compact,with its 300 DPI resolution and large memory offers a very high printing quality. Loading the label rolls and ribbon will be really easy.

The System is able to generate a personalized **REPORT** that includes a list containing all details of the label you printed. You can print and keep it in a store to have always a trace of the sterilization cycles you made, and be sure that everything have been done in a correct way.

	E	F	G	H	I
	ITEM	STERILIZER	STERILIZATION DATE	EXPIRY DATE	CYCLE NO
00	Hip Kit	A	28/05/2018 00:00	27/07/2018 00:00	142
01	Femur kit	D	28/05/2018 00:00	27/07/2018 00:00	123
06	Hand kit	F	28/05/2018 00:00	27/07/2018 00:00	142

Use the Copernico 2D Scan reader to saving time making your documentation label! With just a click you will have all gaps filled with all details to make the new label.

Ink Ribbon

Colore NERO
Resistente al Vapore
Black Color
STEAM Proof

Each thermal transfer printer need its ink ribbon to print labels.

Available in different sizes and colour for any need

It is possible to customize and implement any measure and label printing.

Made in Italy