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Release Date: 2/4/2022

REV AUTHORED BY CHRISTOPHER BAILEY-GATES	DATE 28JAN2022	  SIGNATURES ON FILE		
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PROPRIETARY: This document contains proprietary data of Hologic, Inc. No disclosure, reproduction or use of any part thereof may be made except by written permission from Hologic.		TITLE EU DECLARATION OF CONFORMITY	DOCUMENT NUMBER EUDOC-T5000	REV 001
		SIZE A	SHEET 1 OF 1	

REF:	Product /Trade Name:	Description:
ASY-05528	ThinPrep 5000 Processor	AutoLoader Ready
RM-ASY-05528		AutoLoader Ready, Refurbished
ASY-03098	ThinPrep 5000 Processor AutoLoader	
RM-ASY-03098		Refurbished
71362-001	ThinPrep 5000 Processor	Benchtop
71362-002		Benchtop, Refurbished
71914-001	ThinPrep 5000 Processor Installation Kit	
ASY-08988	ThinPrep 5000 Processor AutoLoader Accessory Kit	

Basic UDI-DI: 54200455CYTPROCESSOR68

Intended Purpose:	The ThinPrep 5000 Processor is part of the ThinPrep System. It is used to prepare ThinPrep microscope slides from ThinPrep PreservCyt vials for use as a replacement for the conventional method of Pap smear preparations for screening for the presence of atypical cells, cervical cancer, or its precursor lesions (Low-grade Squamous Intraepithelial Lesions, High-grade Squamous Intraepithelial Lesions) as well as all other cytologic categories as defined by The Bethesda System for Reporting Cervical Cytology. Also for preparation of ThinPrep microscope slides from non-gynecologic (Non-Gyn) samples, including urine samples. For professional use.	
	Hologic, Inc. 250 Campus Drive Marlborough, MA 01752, USA 1 (800) 442-9892, +1 (508)-263-2900, www.hologic.com	
SRN:	US-MF-000001677	
EC REP	Hologic BV Da Vincilaan 5 1930 Zaventem, Belgium	
SRN:	BE-AR-000000127	

DOCUMENT NUMBER
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We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

■ Regulation (EU) 2017/746 on in vitro diagnostic medical devices

■ Other Directive as applicable for the devices

RoHS' Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Risk Class A ☒ B ☐ C ☐ D ☐

Conformity Route:

ANNEX I & II+III (non sterile class A)



Signature

Christine E Nichols
Director Regulatory Affairs PRRC

Marlborough MA 11 May 2022
Issued in [place] & Date



Declarație de Conformitate UE

REF:	Produs /Denumire comercială:	Descriere:
ASY-05576	Dispozitiv de colorare Compass	
RM-ASY-05576		Recondiționat

Nr. UDI-DI de bază: 54200455CYTCOMPASS2D

Scopul intenționat:	Dispozitivul de colorare Compass este un aparat automat de colorare destinat utilizării în laboratoarele de citologie/patologie anatomică ca unitate independentă, cu montare pe banc de lucru, pentru colorarea mostrelor histologice și citologice pe lame. Pentru uz profesional.	
	Hologic, Inc. 250 Campus Drive Marlborough, MA 01752, SUA 1 (800) 442-9892, +1 (508)-263-2900, www.hologic.com	
SRN:	US-MF-000001677	
	Hologic BV Da Vincilaan 5 1930 Zaventem, Belgia	
SRN:	BE-AR-000000127	
Noi, în calitate de producători ai dispozitivului/dispozitivelor, ne asumăm întreaga responsabilitate și prin prezenta declaram că produsul/produsele menționat(e) mai sus îndeplinește/îndeplinesc prevederile următoarelor Regulament(e)/Directive: ■ Regulamentul (UE) 2017/746 privind dispozitivele medicale de diagnostic in vitro ■ Alte Directive aplicabile pentru dispozitive Directiva RoHS 2011/65/UE privind restricționarea utilizării anumitor substanțe periculoase în echipamentele electrice și electronice. Clasa de risc A ☒ B ☐ C ☐ D ☐		

NUMĂRUL DOCUMENTULUI
EUDOC-COMPASS STAINER

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CORP-00393-T07 Rev. 002



ANEXELE I și II+III (clasa A de dispozitive/produse nesterile)

13 decembrie 2022, Marlborough, MA
Emis la (locul) și data:

Christine E Nichols
Director Departamentul Reglementări, PRRC

Subsemnata, **Pușcă Andra - Maria**, traducător și interpret autorizat pentru limba engleză, titulară a autorizației nr. 27957 /2013 eliberată de Ministerul Justiției, certific exactitatea traducerii din limba Engleză în limba Română cu textul înscrisului ~~original~~/ în copie, prezentat mie.

Undersigned, **Pușcă Andra – Maria**, sworn translator and interpreter for English language, holder of Authorization no. 27957/ 2013 issued by the Ministry of Justice, I hereby certify the exactness of the translation from English language to Romanian language with the text of the document in ~~original~~/ copy, presented before me.

Data/ Date: 12.09.2023

Traducător/ Translator Pușcă Andra – Maria

Autorizație nr./ Authorization no. 27957/ 2013

R O M A N I A

MINISTERUL JUSTIȚIEI/ MINISTRY OF JUSTICE



REF:	Product/Trade Name:	Description:
70208-001	ThinPrep Pap Test Filters	100 PK
70099-001		500 PK
70472-001	ThinPrep UroCyt filters	100 PK
70205-001	ThinPrep Non-Gynecological Filters	100 PK

Basic UDI-DI: 54200455CYTFILTERS2L

Intended Purpose:	ThinPrep Pap Test Filters: ThinPrep Pap Test filters are for use with a ThinPrep processor to collect and transfer a ThinPrep Pap Test PreservCyt sample to a ThinPrep slide as part of the ThinPrep System. For professional use. ThinPrep UroCyt Filters: ThinPrep UroCyt Filters are for use with the ThinPrep processor to collect and transfer a UroCyt PreservCyt urine sample to a ThinPrep slide as part of the ThinPrep System. For professional use. ThinPrep Non-Gynecological Filters: ThinPrep Non-Gynecological (Non-Gyn) filters are for use with the ThinPrep processor to collect and transfer a ThinPrep PreservCyt non-gynecologic sample to a ThinPrep slide as part of the ThinPrep System. For professional use.		
	Hologic, Inc. 250 Campus Drive Marlborough, MA 01752, USA 1 (800) 442-9892, +1 (508)-263-2900, www.hologic.com		
SRN:	US-MF-000001677		
<table border="1" data-bbox="164 1640 383 1724"> <tr> <td>EC</td> <td>REP</td> </tr> </table>	EC	REP	Hologic BV Da Vincilaan 5 1930 Zaventem, Belgium
EC	REP		
SRN:	BE-AR-000000127		

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

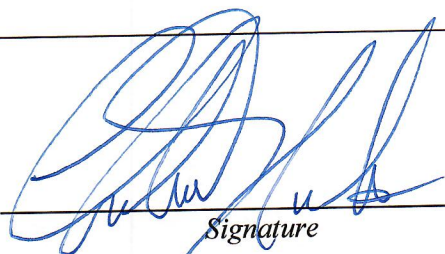
■ Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Risk Class

A ☒ B ☐ C ☐ D ☐

Conformity Route:

ANNEX I & II+III (non sterile class A)


Signature

Christine E Nichols
Director Regulatory Affairs, PRRC

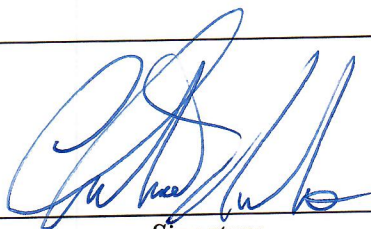
Malden, MA 9/23/2022
Issued in [place] & Date

REF:	Product/Trade Name:	Description:
70303-001	ThinPrep Pap Test Microscope Slides	500 PK
70372-001	ThinPrep Non-Gynecological Microscope Slides	100 PK
70126-002	ThinPrep Arcless Microscope Slides	72 PK
70471-001	ThinPrep UroCyte Microscope Slides	100 PK
70825-001	ThinPrep Imaging System Microscope Slides	500 PK

Basic UDI-DI: 54200455CYTSLIDESGZ

Intended Purpose:	ThinPrep Pap Test microscope slides ThinPrep Pap Test microscope slides are for use with the ThinPrep processors for preparing gynecological specimens as part of the ThinPrep system. For professional use. ThinPrep Non-Gynecological microscope slides ThinPrep Non-Gynecological (Non-Gyn) microscope slides are for use with ThinPrep processors for preparing non-gynecological specimens as part of the ThinPrep system. For professional use. ThinPrep Arcless Microscope slides ThinPrep Arcless microscope slides are for use with ThinPrep processors for preparing cytological specimens as part of the ThinPrep system. Not intended to be used for ThinPrep Pap testing. For professional use. ThinPrep UroCyte Microscope Slides ThinPrep UroCyte microscope slides are for use with ThinPrep processors for preparing urine specimens as part of the ThinPrep system. For professional use. Thin Prep Imaging System Microscope Slides ThinPrep Imaging System microscope slides are for use with ThinPrep processors for preparing cytology specimens as part of the ThinPrep system for diagnosis using ThinPrep Imaging Systems. For professional use.
	Hologic, Inc. 250 Campus Drive Marlborough, MA 01752, USA 1 (800) 442-9892, +1 (508)-263-2900, www.hologic.com

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EC REP	Hologic BV Da Vincilaan 5 1930 Zaventem, Belgium
SRN:	BE-AR-000000127
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives: ■ Regulation (EU) 2017/746 on in vitro diagnostic medical devices Risk Class A ☒ B ☐ C ☐ D ☐	
Conformity Route: ANNEX I & II+III (non sterile class A)	



Signature

Christine E Nichols
Director Regulatory Affairs, PRRC

Marlborough MA, 9/23/2022
Issued in [place] & Date



Declarație de Conformitate UE

REF.	Produs/Denumire comercială	Descriere
70098-002	Soluție ThinPrep PreservCyt pentru test Papanicolau	fiole 250 x 20 ml
ASY-05401		fiole 250 x 20 ml
70406-002	Soluție ThinPrep PreservCyt	flacon 4 x 946 ml
ASY-14753		fiole 100 x 20 ml
ASY-15311	Soluție ThinPrep UroCyt PreservCyt	fiole 100 x 20 ml
ASY-14762	Mediu de recoltare PreservCyt	fiole 100 x 20 ml

UDI-DI de bază: 54200455CYTSOLUTIONBP

Utilizare	Soluție ThinPrep PreservCyt pentru testul Papanicolau Soluția ThinPrep PreservCyt pentru testul Papanicolau este un mediu de transport, conservant și antibacterian pentru probe ginecologice și se utilizează pentru pregătirea lamelelor citologice utilizând un procesor ThinPrep ca parte a sistemului ThinPrep. Soluția ThinPrep PreservCyt pentru testul Papanicolau este, de asemenea, un mediu de recoltare și transport pentru probe ginecologice pentru anumite teste pentru Virusul Papiloma Uman (HPV) și alte infecții cu transmitere sexuală. Consultați instrucțiunile producătorului privind utilizarea soluției PreservCyt pentru recoltarea, transportul și pregătirea probelor pentru aceste teste. Pentru uz profesional.
	Soluție ThinPrep PreservCyt Soluția ThinPrep PreservCyt este un mediu de transport, conservant și antibacterian pentru probe non-ginecologice și se utilizează pentru pregătirea lamelelor citologice utilizând un procesor ThinPrep ca parte a sistemului ThinPrep. Pentru uz profesional.
	Soluție ThinPrep UroCyt PreservCyt Soluția ThinPrep UroCyt PreservCyt este un mediu de transport și conservant pentru probele de urină și se utilizează pentru pregătirea lamelelor citologice utilizând un procesor ThinPrep ca parte a sistemului ThinPrep. Pentru uz profesional.
	Mediu de recoltare PreservCyt Mediul de recoltare PreservCyt este un reactiv pe bază de metanol care servește ca mediu de transport, conservant și antibacterian pentru testarea moleculară a probelor ginecologice. Consultați prospectele producătorilor respectivi pentru instrucțiuni de utilizare a mediului de recoltare PreservCyt pentru recoltarea, transportul și pregătirea probelor pentru utilizarea în testele moleculare specifice. Pentru uz profesional.

NUMĂR DOCUMENT

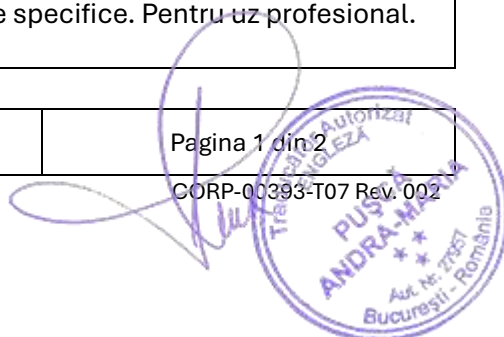
EUDOC – SOLUȚII THINPREP

REV.

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Declarație de Conformitate UE

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SRN:	BE-AR-000000127	

Noi, în calitate de producător al dispozitivului/dispozitivelor, ne asumăm răspunderea doar pentru și prin prezenta declarăm că produsul/produsele menționat(e) mai sus respectă prevederile următoarelor Regulamente/Directive:

- Regulamentul (UE) 2017/746 privind dispozitivele medicale de diagnosticare in vitro.

Clasa de risc ☒ A ☐ B ☐ C ☐ D

Calea de conformitate:

ANEXA I & II + III (clasa A non-sterile)

[semnătură indescifrabilă]

Semnătură

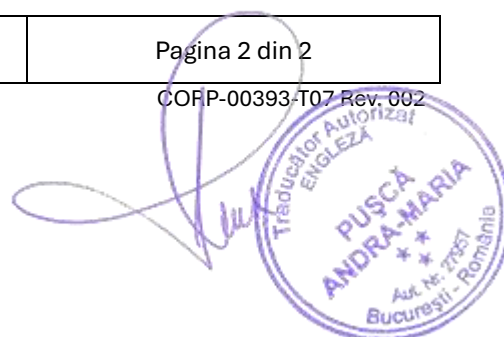
[Marlborough MA, 23.09.2022]

Emis la (locul) și Data

Christine E Nichols
 Director Afaceri de Reglementare, PRRC

NUMĂR DOCUMENT EUDOC – SOLUȚII THINPREP	REV. 002	Pagina 2 din 2
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CORP-00393-T07 Rev. 002



Subsemnata, **Pușcă Andra - Maria**, traducător și interpret autorizat pentru limba engleză, titulară a autorizației nr. 27957 /2013 eliberată de Ministerul Justiției, certific exactitatea traducerii din limba Engleză în limba Română cu textul înscrisului ~~original~~/ în copie, prezentat mie.

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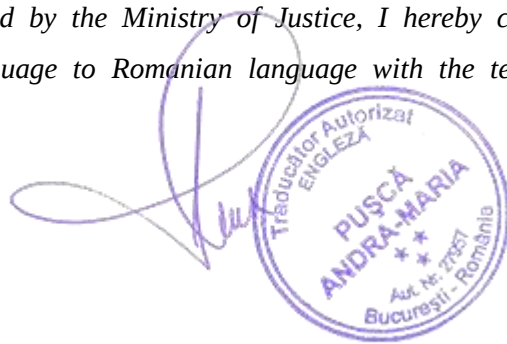
Data/ Date: 27.09.2024

Traducător/ Translator Pușcă Andra – Maria

Autorizație nr./ Authorization no. 27957/ 2013

R O M A N I A

MINISTERUL JUSTIȚIEI/ MINISTRY OF JUSTICE

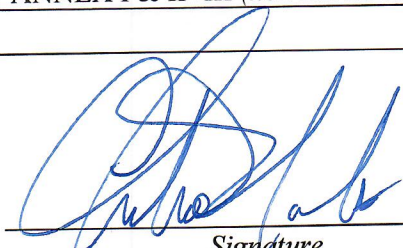


REF:	Product/Trade Name:	Description:
70779-001	ThinPrep Stain Rinse Solution	4.0 L
70780-001	ThinPrep Stain Nuclear Stain	4.0 L
70781-002	ThinPrep Stain Orange G Solution	4.0 L
70782-002	ThinPrep Stain EA Solution	4.0 L
70793-001	ThinPrep Stain Bluing Solution	4.0 L
ASY-04875	ThinPrep Stain Rinse II Solution	4.0 L
ASY-04876	ThinPrep Stain Bluing II Solution	4.0 L

Basic UDI-DI: 54200455CYTSTAIN2G

Intended Purpose:	ThinPrep Stain Rinse solution is intended to be used in a Papanicolaou staining procedure in conjunction with ThinPrep Stain Nuclear Stain, ThinPrep Stain Bluing Solution, ThinPrep Stain Orange G Solution, and ThinPrep Stain EA Solution. For professional use. ThinPrep Stain Nuclear Stain is intended to be used in a Papanicolaou staining procedure in conjunction with any ThinPrep Stain Rinse Solution, ThinPrep Stain Bluing Solution, ThinPrep Stain Orange G Solution, and ThinPrep Stain EA Solution. For professional use. ThinPrep Stain Orange G Solution is intended to be used in a Papanicolaou staining procedure in conjunction with any ThinPrep Stain Nuclear Stain, ThinPrep Stain Rinse Solution, ThinPrep Stain Bluing Solution, and ThinPrep Stain EA Solution. For professional use. ThinPrep Stain EA Solution is intended to be used in a Papanicolaou staining procedure in conjunction with any ThinPrep Stain Nuclear Stain, ThinPrep Stain Rinse Solution, ThinPrep Stain Bluing Solution, and ThinPrep Stain Orange G Solution. For professional use. ThinPrep Stain Bluing Solution is intended to be used in a Papanicolaou staining procedure in conjunction with ThinPrep Stain Nuclear Stain, ThinPrep Stain Rinse Solution, ThinPrep Stain Orange G Solution, and ThinPrep Stain EA Solution. For professional use. ThinPrep Stain Rinse II Solution is intended to be used in Papanicolaou staining procedure in conjunction with ThinPrep Stain Nuclear Stain, ThinPrep Stain Bluing II Solution, ThinPrep Stain Orange G Solution, and ThinPrep Stain EA Solution. For professional use. ThinPrep Stain Bluing II Solution is intended to be used in a Papanicolaou staining procedure in conjunction with ThinPrep Stain Nuclear Stain, ThinPrep Stain Rinse II Solution, ThinPrep Stain Orange G Solution, and ThinPrep Stain EA Solution. For professional use.
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		Hologic, Inc. 250 Campus Drive Marlborough, MA 01752, USA 1 (800) 442-9892, +1 (508)-263-2900, www.hologic.com
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SRN:		BE-AR-000000127
We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives: ■ Regulation (EU) 2017/746 on in vitro diagnostic medical devices Risk Class A ☒ B ☐ C ☐ D ☐ Conformity Route: ANNEX I & II+III (non sterile class A)		



Signature

Christine E Nichols
Director Regulatory Affairs, PRRC

Marlborough, MA 9/23/2022

Issued in [place] & Date