

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée – BP7290
34184 MONTPELLIER Cedex 4 – France
Web: www.horiba.com
Tél.: 33 (0) 4 67 14 15 16

## Déclaration de Conformité Declaration of Conformity

(No.dc200060)

Selon According to ISO 1705051

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HEMATOLOGY REAGENT	ABX DILUENT (20L) / ABX	For application on: ABX Pentra 60, ABX Pentra 60C+, Pentra	ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX	Pentra XL80, Pentra XLR, ABX Pentra 120, ABX Pentra 120	Retic, ABX Pentra DX120, ABX Pentra DF120, Pentra DX	Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500	CT, Yumizen H1500, Yumizen H2500, Yumizen H550	AND 1890 / BAN 1801 A			right
Catégorie du dispositif Category device		Nom du produit	Product name					Modèles	Models	Pays d'origine	Country of origin

# EST CONFORME AUX DIRECTIVES ET NORMES CONFORMS TO DIRECTIVES AND STANDARDS

Directives Directives Classification : General IVD (others) - Outside Annex II and Directives not for self-testing Conformity Assessment Procedure: Annex III / Non-Annex II Standards N/A		98/79/EC - IVD Medical Devices
	Directives	Classification: General IVD (others) - Outside Annex II and
		not for self-testing
Normes N/A Standards		Conformity Assessment Procedure: Annex III / Non-Annex II
Standards	Normes	
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Montpellier, France 06 Juin 2017 June 06<sup>th</sup>, 2017

TEMP-4018 Rev. 12

Christian DUBUC
Directeur
Senior Streetor





HORIBA ABX SAS

Parc Euromédecine

Ruc du Caducée – BP7290 34184 MONTPELLIER Cedex 4 – France Web : www.horiba.com Tél.: 33 (0) 4 67 14 15 16

## Déclaration de Conformité Declaration of Conformity (No.46200556)

Seton According to ISO 17050-1

#### WE THE MANUFACTURER NOUS LE FABRICANT

	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE	
Name	Adresse Address	

# ETABLISSONS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET DECLARONS QUE LE PRODUIT

ESTABLISH UNDER OUR ONLY RESPONSIBILITY THE FOLLOWING DECLARATION AND DECLARE THAT THE PRODUCT

HEMATOLOGY REAGENT	WIITEDIFF (1L) For application on: Yumizen H500 OT, Yumizen H550 Yumizen H550	1210906022	France
Catégorie du dispositif	Nom du produit	Modèles	Pays d'origine
Device category	Product name	<i>Models</i>	Country of origin

# EST CONFORME AUX DIRECTIVES ET NORMES CONFORMS TO DIRECTIVES AND STANDARDS

	Standards
	Normes
Conformity Assessment Procedure: Annex III / Non-Annex II	
not for self-testing	Directives
Classification : General IVD (others) - Outside Annex II and	Directives
98/79/EC – IVD Medical Devices	

Montpellier, France 06 Juin 2017 June 06th, 2017

Christian DUBUC

Directeur Sentrar-Du

TEMP-4018 Rev. 12





Medical HORIBA ABX SAS

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## Déclaration de Conformité Declaration of Conformity (No de200250)

Sclon According to ISO 17050-1

WE THE MANUFACTURER NOUS LE FABRICANT

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ETABLISSONS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET DECLARONS QUE LE PRODUIT ESTABLISH UNDER OUR ONLY RESPONSIBILITY THE FOLLOWING DECLARATION AND DECLARE THAT THE PRODUCT

HEMATOLOGY REAGENT	ABX CLEANER (1L) For application on: ABX Pentra 60, ABX Pentra 60 C+, Pentra ES 60, Pentra MS CRP, ABX Pentra 80, ABX Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XLR, ABX Pentra 120, ABX Pentra 120 Retic, ABX Pentra DX 120, ABX Pentra DY Nexus, Pentra DX 120, ABX Pentra DX Nexus, Pentra DX Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen H500, Yumizen H550 ABX CLEANER (0.5L) For application on: ABX Micros ES 60, ABX Micros CRP, ABX Micros CRP,	0903010, 0903011	France
Catégorie du dispositif Device category	Nom du produit	Modèles	Pays d'origine
	Product name	Models	Country of origin

# EST CONFORME AUX DIRECTIVES ET NORMES CONFORMS TO DIRECTIVES AND STANDARDS

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	Directives	Classification: General IVD (others) - Outside Annex II and
	Directives	not for self-testing
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	Christian DUBCC	
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Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 – France Web: www.horiba.com Tél.: 33 (0) 4 67 14 15 16 HORIBA ABX SAS

#### Déclaration de Conformité Declaration of Conformity (No.de 20022j)

Selon According to ISO 17050-1

#### WE THE MANUFACTURER NOUS LE FABRICANT

HORIBA ABX SAS	Parc Euromédecine	Rue du Caducée – BP7290	34184 MONTPELLIER Cedex 4 - FRANCE
Nom Name	Action	A distriction	71444 (53.3)

#### DECLARONS QUE LE PRODUIT DECLARE THAT THE PRODUCT

ABX IMINOCLAIR  For application on: ABX Micros ABC Vet, ABX Micros 60, ABX Micros ES60, ABX Micros CRP, ABX Micros CRP 200, ABX Pentra 60, ABX Pentra 60 C+, Pentra ES60, Pentra MS60, ABX Pentra 80, ABX Pentra XL 80, ABX Pentra 120, ABX Pentra 120 RETIC, ABX Pentra DX120, ABX Pentra DF 120, ADVIA 60, Micros Care ST	0401005 (0.5 L)
Nom du produit	Modèles
Product name	Models

# EST CONFORME AUX DIRECTIVES ET NORMES CONFORMS TO DIRECTIVES AND STANDARDS

Directives	ives 98/79/EC - IVD Medical Devices
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Normes	
Standards	A/A

Montpellier, France 29 juillet 2011 July 29th, 2011

Bertrand de CASTELNAU Président President

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## Déclaration de Conformité Declaration of Conformity

(No.dc 20031v)

Sclon According to ISO 17050-1

WE THE MANUFACTURER NOUS LE FABRICANT

HORIBA ABX SAS	Parc Euromédecine	Rue du Caducée – BP7290	34184 MONTPELLIER Cedex 4 - FRANCE
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# ETABLISSONS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET

DECLARONS QUE LE PRODUIT ESTABLISH UNDER OUR ONLY RESPONSIBILITY THE FOLLOWING DECLARATION AND DECLARE THAT THE PRODUCT

HEMATOLOGY CONTROL	ABX DIFFTROL For application on: ABX Pentra 60, ABX Pentra 60 C+, Pentra ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL. 80, Pentra XLR, ABX Pentra 120, ABX Pentra 120 RETIC, ABX Pentra DF 120, Pentra DX Nexus, Pentra DF 120, Pentra DX Nexus, Pentra DF Nexus, Pentra DF Nexus, Pentra DF 120, Pentra DF Nexus, Pent	2062203, 2062207, 2062208, 2062011, 2062012, 2062013	USA
Catégorie du dispositif	Nom du produit	Modèles	Pays d'origine
Device category	Product name	Models	Country of origin

# EST CONFORME AUX DIRECTIVES ET NORMES CONFORMS TO DIRECTIVES AND STANDARDS

Directives	Classification: General IVD (others) - Outside Annex II and not
Directives	for self-testing
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Montpellier, France	
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98/79/EC - IVD Medical Devices

June 06th, 2017

Christian DUBUC

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Rue du Caducée — BP7290 34184 MONTPELLIER Cedex 4 — France Web : www.horiba.com Tél. : 33 (0) 4 67 14 15 16

Déclaration de Conformité Declaration of Conformity (No.de 200324)

Selon According to ISO 17050-1

WE THE MANUFACTURER NOUS LE FABRICANT

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ETABLISSONS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET DECLARONS QUE LE PRODUIT ESTABLISH UNDER OUR ONLY RESPONSIBILITY THE FOLLOWING DECLARATION AND DECLARE THAT THE PRODUCT

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		98/79/EC IVD Medical Devices
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Directives		for self-testing
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#### Training Certificate

Horiba Medical Training Center certify that

Mr Daniel TUDOR

has fully followed the training course

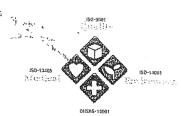
from 21//10/2015 to 23/10/2015

Jülien: EYMARD HÄZOURL Trechnical Trainer

Mr Damiel MUDOR

ier, 23/10/2015 JEV 13154 Patrice LELARGE Int'l Tuaining Center Manager

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### HORIBA ABX SAS

Parc Euromédecine Rue du Caducée - BP 7290 34184 Montpellier cedex 4 - France Tel. : +33 (0)4 67 14 15 16 Fax : +33 (0)4 67 14 15 17

# TRAINING ATTESTATION

To whom it may concern,

This is to certify that **Mr Daniel TUDOR** has regularly followed the training course **YUMIZEN H500** organized in **MONTPELLIER** from 21/10/2015 to 23/10/2015.

The training duration was 17 hours.

Montpellier, 23/10/2015.

This attestation is limited to the professional actions realized for the Company **DIAMEDIX** 

Mr Daniel TUDOR

Trainee

Patrice LELARGE Training Center Manager

Julien EYMARD HAZOURLI Technical Trainer