

Déclaration de Conformité Declaration of Conformity

(No.de200060)

Selon
According to ISO 17050-1

NOUS LE FABRICANT WE THE MANUFACTURER

Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

**ETABLISSEONS 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**

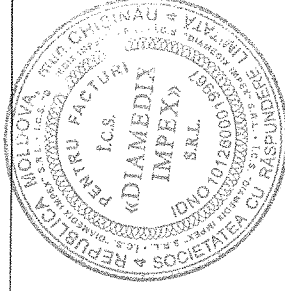
Catégorie du dispositif <i>Category device</i>	HEMATOLOGY REAGENT ABX DILUENT (20L) / ABX DILUENT (10L)
Nom du produit <i>Product name</i>	For application on : ABX Pentra 60, ABX Pentra 60C+, Pentra ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL80, Pentra XLR, ABX Pentra 120, ABX Pentra 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
Modèles <i>Models</i>	0901020 / 0901010
Pays d'origine <i>Country of origin</i>	France

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

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

Montpellier, France
06 Juin 2017
June 06th, 2017

Christian DUBUC
Directeur
Senior Director



TEMP-4018 Rev.12

Déclaration de Conformité Declaration of Conformity

(No.de20055e)

Selon
According to ISO 17050-1

NOUS LE FABRICANT WE THE MANUFACTURER

Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

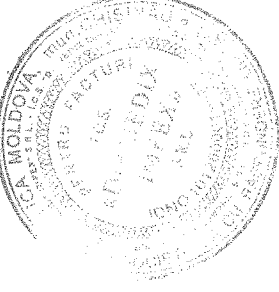
**ETABLISSEMENTS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET
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Catégorie du dispositif <i>Device category</i>	HEMATOLOGY REAGENT
Nom du produit <i>Product name</i>	WHITEDIFF (IL) For application on : Yumizen H500 OT, Yumizen H500 CT, Yumizen H550
Modèles <i>Models</i>	1210906022
Pays d'origine <i>Country of origin</i>	France

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

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

Montpellier, France
06 Juin 2017
June 06th, 2017



Christian DUBUC
Directeur
Senior-Director

TEMP-4018 Rev.12

HORIBA

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Parc Euromédecine
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34184 MONTPELLIER Cedex 4 – France
Web : www.horiba.com
Tel. : 33 (0) 4 67 14 15 16

Déclaration de Conformité Declaration of Conformity

(No. dlc2002.56)

Selon
According to ISO 17050-1

**NOUS LE FABRICANT
WE THE MANUFACTURER**

Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

**ETABLISSEMENTS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET
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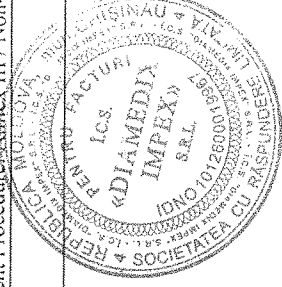
Catégorie du dispositif <i>Device category</i>	HEMATOLOGY REAGENT ABX CLEANER (1L) For application on : ABX Pentra 60, ABX Pentra 60 C+, Pentra ES 60, Pentra MS 60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XLR, ABX Pentra I20, ABX Pentra I20 Retic, ABX Pentra DX I20, ABX Pentra DF I20, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen H1500, Yumizen H2500, Yumizen H550
Nom du produit <i>Product name</i>	ABX CLEANER (0.5L) For application on : ABX Micros ES 60, ABX Micros CRP, ABX Micros CRP 200
Modèles <i>Models</i>	0903010, 0903011
Pays d'origine <i>Country of origin</i>	France

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

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

Montpellier, France
06 Juin 2017
June 06th, 2017

Christian DUBUC
Directeur
Senior Director



TEMP-4018 Rev.12

HORIBA Medical

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Déclaration de Conformité Declaration of Conformity

(No.de 20022j)

Selon
According to ISO 17050-1

NOUS LE FABRICANT WE THE MANUFACTURER

Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédécine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

DECLARONS QUE LE PRODUIT DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX MINOCLAIR 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
Modèles <i>Models</i>	0401005 (0.5 L)

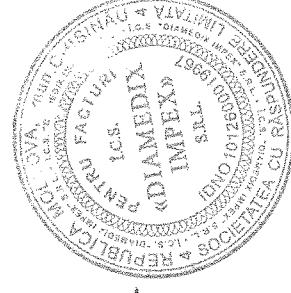
EST CONFORME AUX DIRECTIVES ET NORMES CONFORMS TO DIRECTIVES AND STANDARDS

Directives <i>Directives</i>	98/79/EC – IVD Medical Devices
Normes <i>Standards</i>	N/A

Montpellier, France
29 juillet 2011
July 29th, 2011



Bertrand de CASTELNAU
Président
President



CORP-FORM-0018 Rev.7

HORIBA

Medical

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Déclaration de Conformité Declaration of Conformity

(No.de 2003IV)

Scelon
According to ISO 17050-1

NOUS LE FABRICANT WE THE MANUFACTURER

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

**ETABLISSEONS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET
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Catégorie du dispositif Device category	HEMATOLOGY CONTROL
Nom du produit Product name	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 DX120, ABX Pentra DF 120, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen H1500, Yumizen H2500, Yumizen H550
Modèles Models	2062203, 2062207, 2062208, 2062011, 2062012, 2062013
Pays d'origine Country of origin	USA

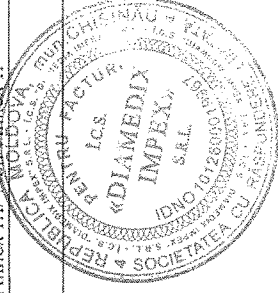
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Directives Directives	98/79/EC – IVD Medical Devices Classification : General IVD (others) - Outside Annex II and not for self-testing Conformity Assessment Procedure: Annex III/ Non-Annex II
Normes Standards	N/A

Montpellier, France
06 Juin 2017
June 06th, 2017

Christian DUBUC

Directeur
Senior Director



TEMP-4018 Rev.12

HORIBA

M e d i c a l

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Parc Euromédecine

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34184 MONTPELLIER Cedex 4 – France

Web : www.horiba.com

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Déclaration de Conformité *Declaration of Conformity*

(No. de 20032u)

Selon
According to ISO 17050-1

NOUS LE FABRICANT *WE THE MANUFACTURER*

Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

**ETABLISSEONS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET
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Catégorie du dispositif <i>Device category</i>	HEMATOLOGY CALIBRATOR
Nom du produit <i>Product name</i>	ABX MINOCAL For application on : ABX Micros 45, ABX Micros ABC Vet, ABX Micros 60, ADVIA 60, ABX Micros ES60, ABX Micros ESV60, Scil Vet ABC Plus, ABX Micros CRP, ABX Micros CRP 200, ABX Pentra 60, ABX Pentra 60 C+, Pentra ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XL.R, ABX Pentra 120, ABX Pentra 120 RETIC, ABX Pentra DX120, ABX Pentra DF 120, Micros Care ST, Microsemi CRP, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen H1500, Yumizen H2500, Yumizen H550
Modèles <i>Models</i>	2032002
Pays d'origine <i>Country of origin</i>	USA

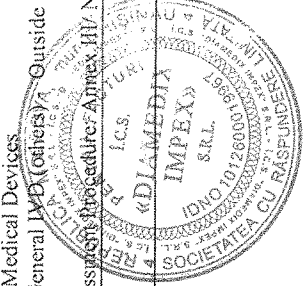
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Directives <i>Directives</i>	98/79/EC – IVD Medical Devices Classification : General IVD (others) Outside Annex II and not for self-testing Conformity Assessment Procedure: Annex III/ Non-Annex II
Normes <i>Standards</i>	N/A

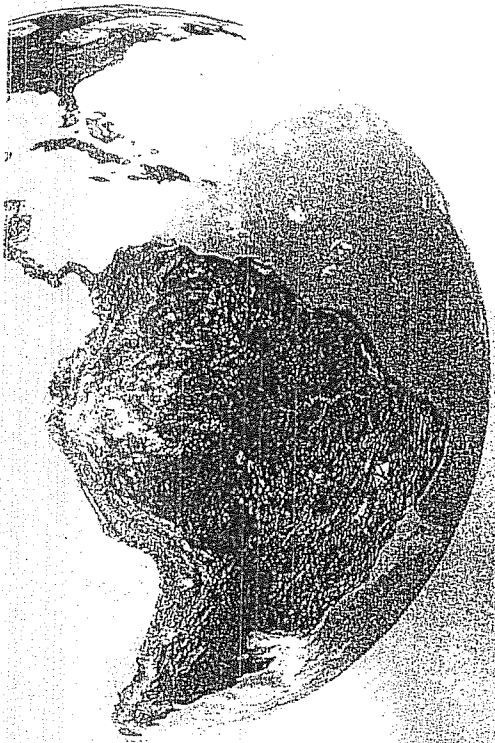
Montpellier, France
06 Juin 2017
June 06th, 2017



Christian DUBUC
Director
Senior Director



TEMP-4018 Rev.12



Training Certificate

Horiba Medical Training Center certify that

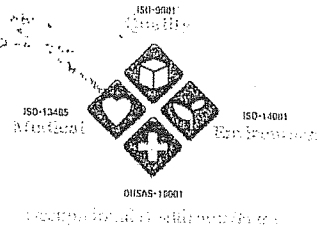
Mr Daniel TUDOR
has fully followed the training course
YUMIZEN H500
from 21/10/2015 to 23/10/2015

Julien EYMARD HAZOURLI
Technical Trainer

Mr Daniel TUDOR
Trainee

Patrice LEBARGE
Int'l Training Center Manager

This attestation is limited to the professional actions realized for :
the Company **DIAMEDIX IMPEX SA**.



21/10/2015
JE 13154
39 Rev.9

HORIBA

Medical

HORIBA ABX SAS

Parc Euromédecine

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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**.

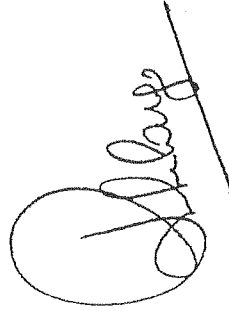
The training duration was **17 hours**.

Montpellier, **23/10/2015**.

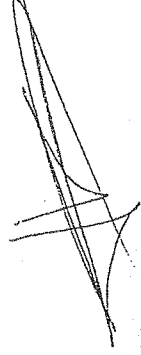
This attestation is limited to the professional actions realized for the Company **DIAMEDIX IMPEX SA**.



Mr Daniel TUDOR
Trainee



Patrice LELARGE
Training Center Manager



Julien EYMARD HAZOURLI
Technical Trainer