

Déclaration de Conformité Declaration of Conformity

(No.de:200060)

Selon
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

**ETABLISSEMENTS 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**

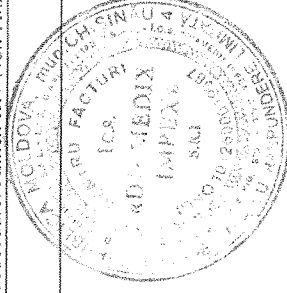
Catégorie du dispositif Category device	HEMATOLOGY REAGENT ABX DILUENT (20L) / ABX DILUENT (10L) For application on : ABX Pentra 60, ABX Pentra 60C+, Pentra ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL80, Pentra XLR, ABX Pentra 120, ABX Pentra 120 Retie, ABX Pentra DX120, ABX Pentra DF120, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen HI500, Yumizen H2500, Yumizen H550
Nom du produit Product name	0901020 / 0901010
Modèles Models	France
Pays d'origine Country of origin	

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

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

Déclaration de Conformité Declaration of Conformity

(No.de20055c)

Selam
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

ETABLISSEMENT 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

M e d i c a l
HORIBA ABX SAS
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Rue du Caducée – BP7290
34184 MONTPELLIER Cedex 4 – France
Web : www.horiba.com
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Déclaration de Conformité Declaration of Conformity

(No.de200256)

Selon
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 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 XLJR, ABX Pentra 120, ABX Pentra 120 Retic, ABX Pentra DX 120, ABX Pentra DF 120, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen H1500, Yumizen H2500, Yumizen H550
Nom du produit Product name	ABX CLEANER (0.5L) For application on : ABX Micros ES 60, ABX Micros CRP, ABX Micros CRP 200
Modèles Models	0903010, 0903011
Pays d'origine Country of origin	France

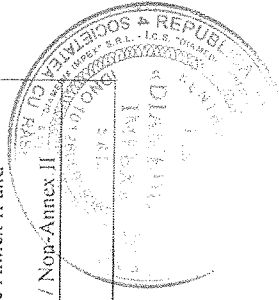
**EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS**

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 / Nop-Annex II
Normes Standards	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.dc200221)

Selon
According to ISO 17050-1**NOUS LE FABRICANT
WE THE MANUFACTURER**

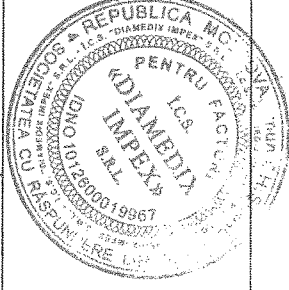
Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

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Catégorie du dispositif <i>Device category</i>	HEMATOLOGY REAGENT
Nom du produit <i>Product name</i>	ABX MINOCLAIR (0.5L) For application on : ABX Micros ABC Vet, ABX Micros 60, ABX Micros ES60, Micros Care ST, ABX Micros CRP, ABX Micros CRP 200, Microsemi CRP, 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, ADVIA 60, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen H1500, Yumizen H2500, Yumizen H550
Modèles <i>Models</i>	0401005
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 : IVD Devices for self-testing Outside Annex II and for self-testing (on Micros Care ST only) Conformity Assessment Procedure : Annex III, section 6 / Non-Annex II Notified body name : SGS UK / Notified body number : 0120
Normes <i>Standards</i>	ISO 14971 :2012 EN 18113-2 :2011 EN 18113-4 :2011 EN 980 :2008 EN 13612 :2002 EN 13485 :2012 / ISO 9001 :2008 EN 13640 :2002 EN 13641 :2002 EN 13532 :2002

Montpellier, France
06 Juin 2017
June 06th, 2017**Christian DUBUC**Directeur
Senior Director

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Déclaration de Conformité Declaration of Conformity

(No.de 20031v)

Selon
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 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 CH, 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

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

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
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Directeur
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HORIBA

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Parc Euromédecine

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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

**ETABLISSEMENT SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET
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Catégorie du dispositif <i>Device category</i>	HEMATOLOGY CALBRATOR
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 XLR, 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

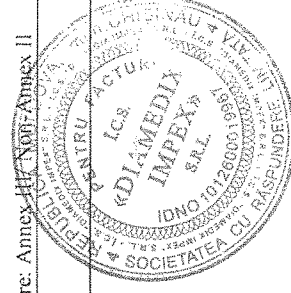
**EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS**

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 II II Non-Annex II
Normes <i>Standards</i>	N/A

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