

HORIBA

Medical

HORIBA ABX SAS
Pôle 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. dc201006a)

Selon
According to ISO 17080-1

NOUS LE FABRICANT WE THE MANUFACTURER

Nom Name	HORIBA ABX SAS
Adresse Address	Pôle 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

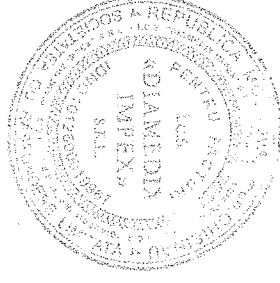
Catégorie du dispositif Category device	HEMATOLOGY REAGENT
Nom du produit Product name	ABX DILUENT (20L) / ABX DILUENT (10L) For application on : ABX Pentra 60, ABX Pentra 60C -, Pentra ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL80, Pentra XLJR, ABX Pentra 120, ABX Pentra 120 Reitc, ABX Pentra DX120, ABX Pentra DF120, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen H1500, Yumizen H2500, Yumizen H450
Modèles Models	0901020 / 0901010
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 / Non-Annex II
Normes Standards	N/A

Montpellier, France
06 Juin 2017
June 06th, 2017

Christian DUBUC
Directeur
Senior Director



TEMP-4018 Rev.12

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Parc Euromédecine

Rue du Caducée - BP7290

34184 MONTPELLIER Cedex 4 - France

Web : www.horiba.com

Tel. : 33 (0) 4 67 14 15 16

Déclaration de Conformité Declaration of Conformity

(No.de20014s)

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

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

Nom du produit Product name	ABX LYSEBIO (0.4L) 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, Microsemi CRP ABX LYSEBIO (1L), For application on : ABX Pentra 80, ABX Pentra XL 80, ABX Pentra 120, ABX Pentra 120 RETIC, ABX Pentra DX120, ABX Pentra DF 120, Microsemi CRP, Pentra DX Nexus, Pentra DF Nexus, Pentra XLR, Yumizen H1500, Yumizen H2500
Modèles Models	0906013 0906012
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 / Non-Annex II
Normes Standards	N/A

Montpellier, France

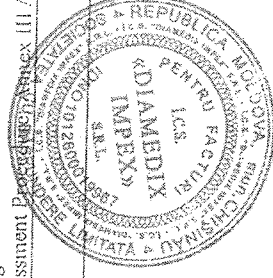
05/Avril 2017

April 05th, 2017

Christian DUBUC

Directeur

Senior Director



TEMP-4018 Rev.9

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Déclaration de Conformité Declaration of Conformity

(No.de20017k)

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

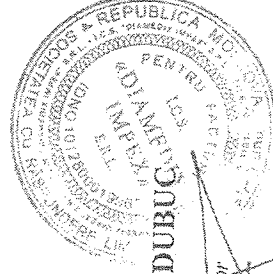
DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit Product name	ABX EOSINOFIX (1L) 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
Modèles Models	0206010
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 / Non-Annex II
Normes Standards	N/A

Montpellier, France
03 Février 2016
February 03rd, 2016



Christian DUBUC
Directeur
Senior Director

TEMP-4018 Rev.9

Déclaration de Conformité Declaration of Conformity

(No.dc20016i)

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

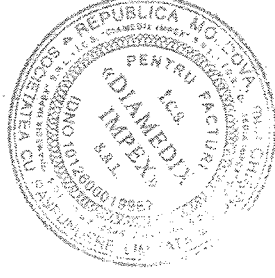
Nom du produit Product name	ABX BASOLYSE II (IL) For application on : ABX Pentra 60, ABX Pentra 60C ¹⁴ , Pentra ES 60, Pentra MS 60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XL.R
Modèles Models	0906003
Pays d'origine Country of origin	France

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
Normes Standards	Conformity Assessment Procedure: Annex III / Non-Annex II N/A

Montpellier, France
03 Février 2016
February 03rd, 2016

Christian DUBEC
Directeur
Senior Director



TEMP-4018 Rev.9

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M e d i c a l

HORIBA ABX SAS

Parc Euro Médécine

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 2002.50)

Selon
According to ISO 17050-1

**NOUS LE FABRICANT
WE THE MANUFACTURER**

Nom Name	HORIBA ABX SAS
Adresse Address	Parc Euro Médécine 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 Device category	HEMATOLOGY REAGENT
Nom du produit Product name	ABX CLEANER (1L) For application on : ABX Pentra 60, ABX Pentra 60 CP, Pentra ES 60, Pentra MS 60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XLIR, ABX Pentra 120, ABX Pentra 120 Rele, 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
Modèles Models	ABX CLEANER (0.5L) For application on : ABX Micros ES 60, ABX Micros CRP, ABX Micros CRP 200
Pays d'origine Country of origin	0903010, 0903011 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 / Non-Annex II
Normes Standards	N/A

Montpellier, France

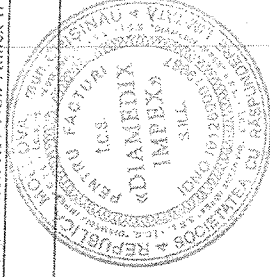
06 juin 2017

June 06th, 2017

Christian DUBUC

Directeur

Senior Director



TEMP-4018 Rev.12

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Tél. : 33 (0) 4 67 14 15 16

Déclaration de Conformité Declaration of Conformity

(No. de 20022))

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

DECLARONS QUE LE PRODUIT DECLARE THAT THE PRODUCT

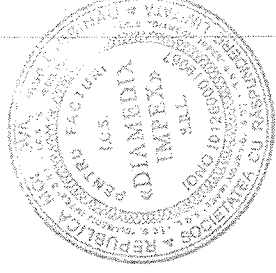
Nom du produit Product name	ABX MINOCLAIR For application on : ABX Micros ABC Vet, ABX Micros 60, ABX Micros ES60, ABX Micros CRP, ABX Micros CRP 200, ABX Pentra 60, ABX Pentra 60 C+, Pentra ES60, Pentra MS60, ABX Pentra 80, ABX Pentra XL 80, ABX Pentra 120, ABX Pentra 120 RETIC, ABX Pentra DX120, ABX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

EST CONFORME AUX DIRECTIVES ET NORMES CONFORMS TO DIRECTIVES AND STANDARDS

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

Montpellier, France
29 juillet 2011
July 29th, 2011


Bertrand de CASTELNAU
Président
President



CORP-FORM-0013 Rev.7

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34184 MONTPELLIER Cedex 4 – France

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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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DECLARE THAT THE PRODUCT**

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 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

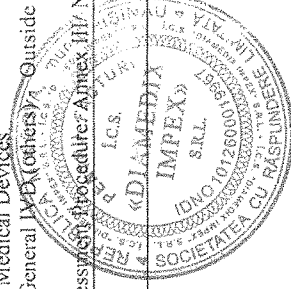
**EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS**

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

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

ETABLISSEMENTS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET
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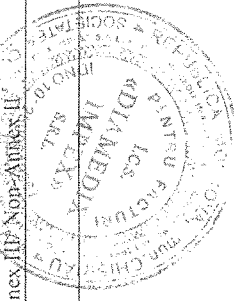
Catégorie du dispositif <i>Device category</i>	HEMATOLOGY CONTROL
Nom du produit <i>Product name</i>	ABX DIFFTROL For application on : ABX Pentra 60, ABX Pentra 60 C+, Pentra ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XLR, ABX Pentra 120, ABX Pentra 120 RETIC, ABX Pentra DX120, ABX Pentra DF 120, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OF, Yumizen H500 CT, Yumizen H1500, Yumizen H2500, Yumizen H550
Modèles <i>Models</i>	2062203, 2062207, 2062208, 2062011, 2062012, 2062013
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/ Non-Annex II
Normes <i>Standards</i>	N/A

Montpellier, France
06 Juin 2017
June 06th, 2017

Christian DUBUC
Directeur
Senior Director



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