



# HORIBA

Medical

HORIBA ABX SAS

Parc Euromédecine

Rue du Caducée – BP7290

34184 MONTPELLIER Cedex 4 – France

Web : [www.horiba.com](http://www.horiba.com)

Tél. : 33 (0) 4 67 14 15 16

## Déclaration de Conformité Declaration of Conformity

(No.dtc20014s)

Selon  
According to ISO 17050-1

**NOUS LE FABRICANT  
WE THE MANUFACTURER**

Nom Name	<b>HORIBA ABX SAS</b>
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	<b>ABX LYSEBIO (0.4L)</b> For application on : ABX Pentra 60, ABX Pentra 60 Ct, Pentra ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XLR, Microsemi CRP <b>ABX LYSEBIO (1L),</b> 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	<b>0906013</b> <b>0906012</b>
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

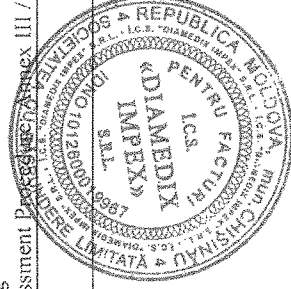
05 Avril 2017

April 05<sup>th</sup>, 2017

**Christian DUBUC**

Directeur

Senior Director



TEMP-4018 Rev.9

## Déclaration de Conformité Declaration of Conformity

(No.dc20017k)

Selon  
According to ISO 17050-1

### NOUS LE FABRICANT WE THE MANUFACTURER

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

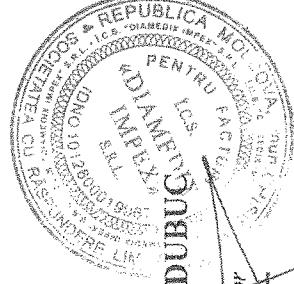
### DECLARONS QUE LE PRODUIT DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	<b>ABX EOSINOFIX (IL)</b> 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 <i>Models</i>	<b>0206010</b>
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  
03 Février 2016  
February 03<sup>rd</sup>, 2016



**Christian DUBUC**  
Directeur  
Senior Director

TEMP-4018 Rev.9

## Déclaration de Conformité Declaration of Conformity

(No.de200161)

Selon  
According to ISO 17050-1

### NOUS LE FABRICANT WE THE MANUFACTURER

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

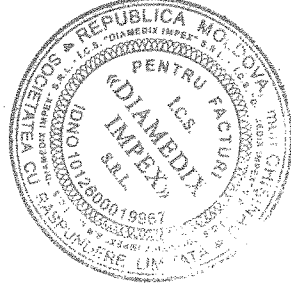
### DECLARONS QUE LE PRODUIT DECLARE THAT THE PRODUCT

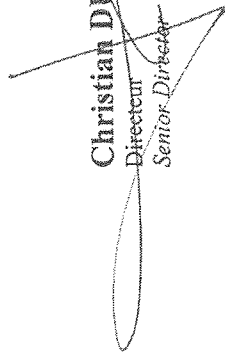
Nom du produit <i>Product name</i>	<b>ABX BASOLYSE II (1L)</b> For application on : ABX Pentra 60, ABX Pentra 60C+, Pentra ES 60, Pentra MS 60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XLR
Modèles <i>Models</i>	<b>0906003</b>
Pays d'origine <i>Country of origin</i>	France

### 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  
03 Février 2016  
February 03<sup>rd</sup>, 2016



  
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## Déclaration de Conformité Declaration of Conformity

(No.de2002.56)

Selon  
According to ISO 17050-1

**NOUS LE FABRICANT  
WE THE MANUFACTURER**

Nom Name	<b>HORIBA ABX SAS</b>
Adresse Address	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 Device category	<b>HEMATOLOGY REAGENT</b>
Nom du produit Product name	<b>ABX CLEANER (1L)</b> 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 120, ABX Pentra 120 Retie, 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	<b>ABX CLEANER (0.5L)</b> For application on : ABX Micros ES 60, ABX Micros CRP, ABX Micros CRP 200
Pays d'origine Country of origin	<b>0903010, 0903011</b> 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 06<sup>th</sup>, 2017

**Christian DUBUC**

Directeur

Senior Director

TEMP-4018 Rev.12

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**HORIBA**

# Déclaration de Conformité Declaration of Conformity

(No.de20022t)

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

Nom <i>Name</i>	<b>HORIBA ABX SAS</b>
Adresse <i>Address</i>	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**

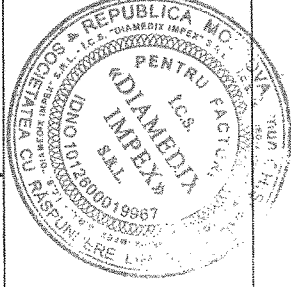
Catégorie du dispositif <i>Device category</i>	<b>HEMATOLOGY REAGENT</b>
Nom du produit <i>Product name</i>	<b>ABX MINOCLAIR (0.5L)</b> For application on : ABX Micros ABC Vet, ABX Micros 60, ABX Micros ES60, Micros Care ST, ABX Micros CRP, ABX Micros CRP 200, Microsemi CRP, ABX Pentra 60, ABX Pentra 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>	<b>0401005</b>
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 06<sup>th</sup>, 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	<b>HORIBA ABX SAS</b>
Adresse address	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 Device category	<b>HEMATOLOGY CONTROL</b>
Nom du produit Product name	<b>ABX DIFFTROL</b> 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 Models	<b>2062203, 2062207, 2062208, 2062011, 2062012, 2062013</b>
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 II / Non-Annex II
Normes Standards	N/A

Montpellier, France  
06 Juin 2017  
June 06<sup>th</sup>, 2017

**Christian DUBUC**  
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TEMP-4018 Rev.12

