

## HORIBA ABX SAS

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

TO: Agency of Medicine and Medical Devices from Republic of Moldova,  
Registering of Medical Device Department

Montpellier, the 20<sup>th</sup> of January 2016

Dear Sirs,

**HORIBA ABX SAS** undersigned, headquartered in France, *Parc Euromédecine Street, Rue de Caducée, B.P. 7290-34184 Montpellier, Cedex 4 France*, registered at the *Registre du Commerce et des Sociétés de Montpellier* under no. 328 031 042, confirms that we have empowered ICS Diamedix Impex SRL to be the official Authorized Representative for the registration of some products in the Republic of Moldova.

**HORIBA ABX SAS** is a European manufacturer of non-implantable in vitro diagnostics devices with ISO 9001, 14001, 13485, 18001 certifications. **HORIBA ABX SAS** distributes its products in over 110 countries on all five continents, complying with the national and international conformity (standardisation): CE IVD, US FDA, CMDCAS, ANVISA,...

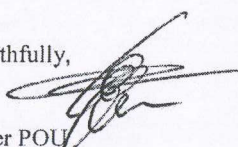
According to the agreement signed between **HORIBA ABX SAS** and ICS Diamedix Impex SRL, **HORIBA** shall provide to the Authorized Representative, for the registration of the concerned medical devices, technical documentation relevant to market surveillance investigation being undertaken by the Medicines and Medical Devices Agency in the Republic of Moldova.

Regarding the registration of the products listed in Annex 1 hereto attached, in terms of meeting the requirements of Annex 3 (technical files), to Order AMDM nr. A07PS-01Rg04-112 from 03.07.2014, points:

3. Information on design and manufacturing
4. General requirements on safety and performance
5. Risk-benefit analysis and risk management
6. Verification and validation of product

hereby, we **HORIBA ABX SAS** declare that all these requirements are subject to trade secret of the mentioned product and **HORIBA ABX SAS** holds confidential intellectual property right license, know-how and patent for the production of them.

Yours faithfully,



Mr Olivier POU  
Distributors Network Manager  
**HORIBA ABX SAS**



# HORIBA

Medical

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# Déclaration de Conformité Declaration of Conformity

(No.dc20022t)

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

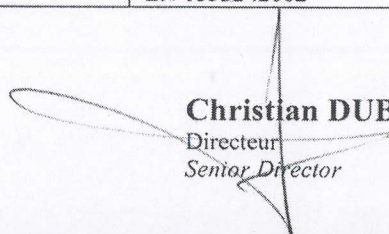
**ETABLISSEMENT SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET  
DECLARONS QUE LE PRODUIT  
ESTABLISH UNDER OUR ONLY RESPONSIBILITY THE FOLLOWING DECLARATION AND  
DECLARE THAT THE PRODUCT**

Catégorie du dispositif Device category	<b>HEMATOLOGY REAGENT</b>
Nom du produit Product name	<b>ABX 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 Models	<b>0401005</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 : 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 Standards	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



TEMP-4018 Rev.12



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## Déclaration de Conformité Declaration of Conformity

(No.de20006o)

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

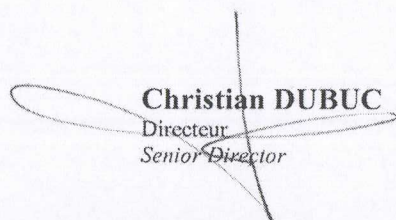
**ETABLISSEMENTS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET  
 DECLARONS QUE LE PRODUIT  
 ESTABLISH UNDER OUR ONLY RESPONSIBILITY THE FOLLOWING DECLARATION AND  
 DECLARE THAT THE PRODUCT**

Catégorie du dispositif Category device	<b>HEMATOLOGY REAGENT</b>
Nom du produit Product name	<b>ABX DILUENT (20L) / ABX DILUENT (10L)</b> 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 Models	<b>0901020 / 0901010</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  
 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.dc 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

**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 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 OT, 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 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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## Déclaration de Conformité Declaration of Conformity

(No.dc20016i)

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 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 Models	<b>0906003</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  
 03 Février 2016  
 February 03<sup>rd</sup>, 2016

  
**Christian DUBUC**  
 Directeur  
 Senior Director



TEMP-4018 Rev.9



HORIBA ABX SAS  
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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	<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 EOSINOFIX (1L)</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 Models	<b>0206010</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  
 03 Février 2016  
 February 03<sup>rd</sup>, 2016

**Christian DUBUC**  
 Directeur  
 Senior Director




TEMP-4018 Rev.9



# HORIBA

Medical

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## Déclaration de Conformité Declaration of Conformity

(No.dc20014s)

Selon  
According to ISO 17050-1

**NOUS LE FABRICANT  
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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 C+, 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



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