HORIBA
Medical

**HORIBA ABX SAS**
Parc Euromédecine
Rue du Caducée - BP 7290
34184 Montpellier cedex 4 - France
Tel. : +33 (0)4 67 14 15 16
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 20th 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**

REPUBLICA MOLDOVA mun. CHISINAU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

HORIBA
Medical
HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
BP 7290 - 34184 Montpellier cedex 4 - France
Tél. +33 (0)4 67 14 15 16
Fax +33 (0)4 67 14 17 63
RCS Montpellier 328 031 042

HORIBA
Medical

HORIBA ABX SAS
Parc 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.dc20022t)

Selon
*According to* ISO 17050-1

## NOUS LE FABRICANT
## *WE THE MANUFACTURER*

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

## ETABLISSONS 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<br>*Device category* | **HEMATOLOGY REAGENT** |
| Nom du produit<br>*Product name* | **ABX MINOCLAIR (0.5L)**<br>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<br>*Models* | **0401005** |
| Pays d'origine<br>*Country of origin* | France |

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

| | |
|---|---|
| Directives<br>*Directives* | 98/79/EC – IVD Medical Devices<br>Classification : IVD Devices for self-testing Outside Annex II and for self-testing (on Micros Care ST only)<br>Conformity Assessment Procedure : Annex III, section 6 / Non-Annex II<br>Notified body name : SGS UK / Notified body number : 0120 |
| Normes<br>*Standards* | ISO 14971 :2012<br>EN 18113-2 :2011<br>EN 18113-4 :2011<br>EN 980 :2008<br>EN 13612 : 2002<br>EN 13485 :2012 / ISO 9001 :2008<br>EN 13640 :2002<br>EN 13641 :2002<br>EN 13532 :2002 |

Montpellier, France
06 Juin 2017
*June 06th, 2017*

**Christian DUBUC**
Directeur
*Senior Director*

*TEMP-4018 Rev.12*

HORIBA ABX SAS
Parc 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.dc200060)

Selon
*According to* ISO 17050-1

**NOUS LE FABRICANT**
***WE THE MANUFACTURER***

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

**ETABLISSONS 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<br>*Category device* | **HEMATOLOGY REAGENT** |
| Nom du produit<br>*Product name* | **ABX DILUENT (20L) / ABX DILUENT (10L)**<br>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<br>*Models* | **0901020 / 0901010** |
| Pays d'origine<br>*Country of origin* | France |

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

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

Montpellier, France
06 Juin 2017
*June 06th, 2017*

**Christian DUBUC**
Directeur
*Senior Director*

REPUBLICA MOLDOVA mun. CHISINAU
PENTRU FACTURI
I.C.S.
«DIAMEDIX IMPEX»
S.R.L.
IDNO 1012600019967
SOCIETATEA CU RASPUNDERE LIMITATA

*TEMP-4018 Rev.12*

HORIBA ABX SAS
Parc 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.dc 20031v)

Selon
*According to* ISO 17050-1

**NOUS LE FABRICANT**
***WE THE MANUFACTURER***

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

**ETABLISSONS 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<br>*Device category* | **HEMATOLOGY CONTROL** |
| Nom du produit<br>*Product name* | **ABX DIFFTROL**<br>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<br>*Models* | **2062203, 2062207, 2062208, 2062011, 2062012, 2062013** |
| Pays d'origine<br>Country of origin | USA |

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

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

Montpellier, France
06 Juin 2017
*June 06th, 2017*

**Christian DUBUC**
Directeur
*Senior Director*

REPUBLICA MOLDOVA PENTRU FACTURI L.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

*TEMP-4018 Rev.12*

HORIBA ABX SAS
Parc 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.dc20016i)

Selon
*According to* ISO 17050-1

## NOUS LE FABRICANT
## *WE THE MANUFACTURER*

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

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

| | |
|---|---|
| Nom du produit<br>*Product name* | **ABX BASOLYSE II (1L)**<br>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<br>*Models* | **0906003** |
| Pays d'origine<br>*Country of origin* | France |

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

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

Montpellier, France
03 Février 2016
*February 03rd , 2016*

**Christian DUBUC**
Directeur
*Senior Director*

REPUBLICA MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RASPUNDERE LIMITATA

*TEMP-4018 Rev.9*

HORIBA
Medical

HORIBA ABX SAS
Parc 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.dc20017k)

Selon
*According to* ISO 17050-1

## NOUS LE FABRICANT
## *WE THE MANUFACTURER*

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

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

| | |
|---|---|
| Nom du produit<br>*Product name* | **ABX EOSINOFIX (1L)**<br>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<br>*Models* | **0206010** |
| Pays d'origine<br>*Country of origin* | France |

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

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

Montpellier, France
03 Février 2016
*February 03rd, 2016*

**Christian DUBUC**
Directeur
*Senior Director*

REPUBLICA MOLDOVA I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600013367 SOCIETATEA CU RASPUNDERE LIMITATA

*TEMP-4018 Rev.9*

HORIBA
Medical
HORIBA ABX SAS
Parc 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.dc20014s)

Selon
*According to* ISO 17050-1

## NOUS LE FABRICANT
## *WE THE MANUFACTURER*

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

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

| | |
|---|---|
| Nom du produit<br>*Product name* | **ABX LYSEBIO (0.4L)**<br>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<br>**ABX LYSEBIO (1L),**<br>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<br>*Models* | **0906013**<br>**0906012** |
| Pays d'origine<br>*Country of origin* | France |

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

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

Montpellier, France
05 Avril 2017
*April 05th , 2017*

**Christian DUBUC**
Directeur
*Senior Director*

*TEMP-4018 Rev.9*