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

Digitally signed by Marinescu Traian Alin
Date: 2020.03.25 15:44:16 EET
Reason: MoldSign Signature
Location: Moldova

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.de20055c)

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

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 *Device category*	**HEMATOLOGY REAGENT**
Nom du produit *Product name*	**WHITEDIFF (1L)** For application on : Yumizen H500 OT, Yumizen H500 CT, Yumizen H550
Modèles *Models*	**1210906022**
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

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 *Name*	**HORIBA ABX SAS**
Adresse *Address*	Parc Euromédecine Rue du Caducée – BP7290 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 *Device category*	**HEMATOLOGY REAGENT**
Nom du produit *Product name*	**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 *Models*	**0401005**
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 06th, 2017

Christian DUBUC
Directeur
Senior Director

TEMP-4018 Rev.12

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.dc200060)

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

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 *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 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*	**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

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.dc20025o)

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

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 *Device category*	**HEMATOLOGY REAGENT**
Nom du produit *Product name*	**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 XLR, 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 **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 / Non-Annex II
Normes *Standards*	N/A

Montpellier, France
06 Juin 2017
June 06th, 2017

Christian DUBUC
Directeur
Senior Director

TEMP-4018 Rev.12

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.dc 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

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 *Device category*	**HEMATOLOGY CONTROL**
Nom du produit *Product name*	**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 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
June 06th, 2017

Christian DUBUC
Directeur
Senior Director

REPUBLICA MOLDOVA, MUNICIPIUL CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ, PENTRU FACTURĂ, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012800019996

TEMP-4018 Rev.12