

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
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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:

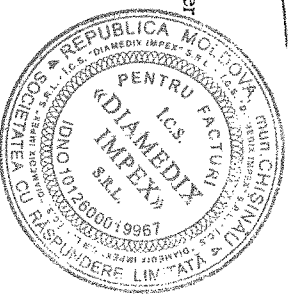
3. Information on design and manufacturing
4. General requirements on safety and performance
5. Risk-benefit analysis and risk management
6. Verification and validation of product

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



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Déclaration de Conformité *Declaration of Conformity*

(No.de20055c)

Selon
According to ISO 17050-1

NOUS LE FABRICANT WE THE MANUFACTURER

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

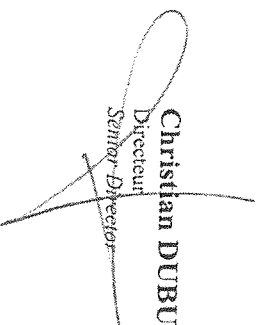
ETABLISSEMENT SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET
DECLARONS QUE LE PRODUIT
ESTABLISH UNDER OUR ONLY RESPONSIBILITY THE FOLLOWING DECLARATION AND
DECLARE THAT THE PRODUCT

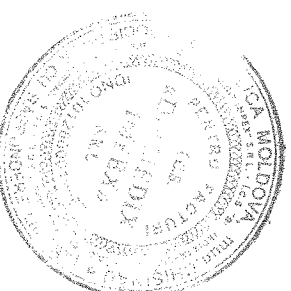
Catégorie du dispositif <i>Device category</i>	HEMATOLOGY REAGENT
Nom du produit <i>Product name</i>	WHITEDIFF (1L) For application on : Yunitizen H500 OT, Yunitizen H500 CT, Yunitizen H550
Modèles <i>Models</i>	1210906022
Pays d'origine <i>Country of origin</i>	France

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

Montpellier, France
06 Juin 2017
June 06th, 2017


Christian DUBUC
Directeur
Senior Director



TEMP-4018 Rev.12

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Déclaration de Conformité Declaration of Conformity

(No.de200220)

Sélon
According to ISO 17050-1

**NOUS LE FABRICANT
WE THE MANUFACTURER**

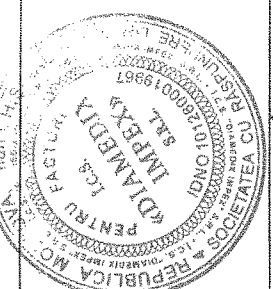
Nom Name	HORIBA ABX SAS
Adresse Address	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

**ETABLISSEONS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET
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Catégorie du dispositif Device category	HEMATOLOGY REAGENT
Nom du produit Product name	ABX MINOCLAIR (0.5L) For application on : ABX Micros ABC Vel, 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 HI 500, 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



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Déclaration de Conformité Declaration of Conformity

(No.dec200060)

Selon
According to ISO 17050-1

NOUS LE FABRICANT WE THE MANUFACTURER

Nom Name	HORIBA ABX SAS
Adresse Address	Parc Euromédécine 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 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 Reite, 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

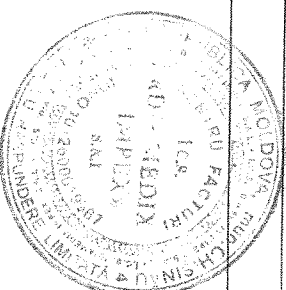
EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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

Montpellier, France
06 Juin 2017
June 06th, 2017

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M e d i c a l

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Déclaration de Conformité *Declaration of Conformity*

(No de200256)

Selon
According to ISO 17050-1

**NOUS LE FABRICANT
WE THE MANUFACTURER**

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

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Catégorie du dispositif <i>Device category</i>	HEMATOLOGY REAGENT
Nom du produit <i>Product name</i>	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 XL R, 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
Modèles <i>Models</i>	ABX CLEANER (0.5L) For application on : ABX Micros ES 60, ABX Micros CRP, ABX Micros CRP 200
Modèles <i>Models</i>	0903010, 0903011
Pays d'origine <i>Country of origin</i>	France

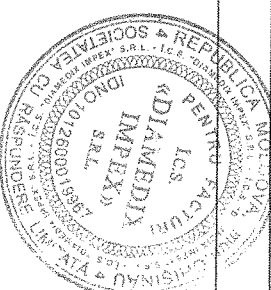
**EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS**

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

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Déclaration de Conformité *Declaration of Conformity*

(No de 20031v)

Selon
According to ISO 17050-1

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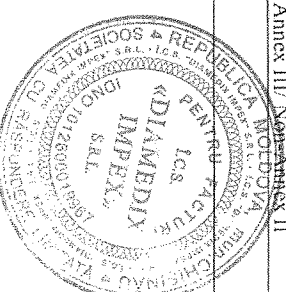
Catégorie du dispositif <i>Device category</i>	HEMATOLOGY CONTROL
Nom du produit <i>Product name</i>	ABX DIFFTROL For application on : ABX Pentra 60, ABX Pentra 60 C+, Pentra ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX Pentra XL 80, Pentra XLR, ABX Pentra 120, ABX Pentra 120 RETIC, ABX Pentra DX120, ABX Pentra DF 120, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, 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
Normes <i>Standards</i>	Conformity Assessment Procedure: Annex III, Non-Annex II N/A

Montpellier, France
06 juin 2017
June 06th, 2017

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TEMP-4018 Rev.12