

**Déclaration de Conformité**  
**Declaration of Conformity**

(No.de200060)

Selon  
According to ISO 17050-1

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

|                           |                                                                                    |
|---------------------------|------------------------------------------------------------------------------------|
| Nom<br><i>Name</i>        | <b>HORIBA ABX SAS</b>                                                              |
| Adresse<br><i>Address</i> | Parc Euromédecine<br>Rue du Caducée – BP7290<br>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**

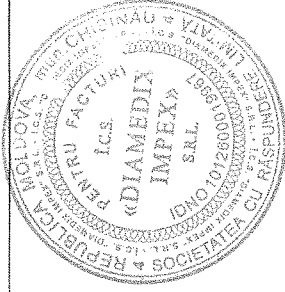
|                                                   |                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Catégorie du dispositif<br><i>Category device</i> | <b>HEMATOLOGY REAGENT</b>                                                                                                                                                                                                                                                                                                                                                                             |
| Nom du produit<br><i>Product name</i>             | <b>ABX DILUENT (20L) / ABX<br/>DILUENT (10L)</b><br>For application on : ABX Pentra 60, ABX Pentra 60C+, Pentra<br>ES60, Pentra MS60, Pentra MS CRP, ABX Pentra 80, ABX<br>Pentra XL80, Pentra XLR, ABX Pentra 120, ABX Pentra 120<br>Retic, ABX Pentra DX120, ABX Pentra DF120, Pentra DX<br>Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500<br>CT, Yumizen H1500, Yumizen H2500, Yumizen H550 |
| Modèles<br><i>Models</i>                          | <b>0901020 / 0901010</b>                                                                                                                                                                                                                                                                                                                                                                              |
| Pays d'origine<br><i>Country of origin</i>        | France                                                                                                                                                                                                                                                                                                                                                                                                |

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

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

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

**Christian DUBUC**  
Directeur  
Senior Director



TEMP-4018 Rev.12

Déclaration de Conformité  
*Declaration of Conformity*

(No.de20055c)

Selon  
According to ISO 17050-1

NOUS LE FABRICANT  
*WE THE MANUFACTURER*

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

ETABLISSEONS SOUS NOTRE SEULE RESPONSABILITE LA DECLARATION SUIVANTE ET  
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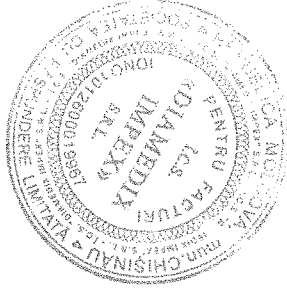
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| Catégorie du dispositif<br><i>Device category</i> | HEMATOLOGY REAGENT                                                                       |
| Nom du produit<br><i>Product name</i>             | WHITEDIFF (1L)<br>For application on : Yumizen H500 OT, Yumizen H500 CT,<br>Yumizen H550 |
| Modèles<br><i>Models</i>                          | 1210906022                                                                               |
| Pays d'origine<br><i>Country of origin</i>        | France                                                                                   |

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

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

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

Christian DUBUC  
Directeur  
*Senior Director*



TEMP-4018 Rev.12

Déclaration de Conformité  
Declaration of Conformity

(No de20025o)

Selon  
According to ISO 17050-1

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WE THE MANUFACTURER

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

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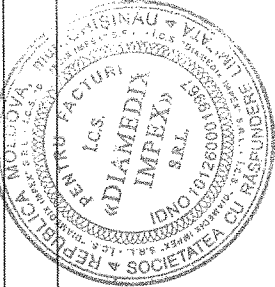
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|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Catégorie du dispositif<br>Device category | HEMATOLOGY REAGENT                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Nom du produit<br>Product name             | ABX CLEANER (1L)<br>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<br>ABX CLEANER (0.5L)<br>For application on : ABX Micros ES 60, ABX Micros CRP, ABX Micros CRP 200 |
| Modèles<br>Models                          | 0903010, 0903011                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 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 06<sup>th</sup>, 2017

Christian DUBUC  
Directeur  
Senior Director



TEMP-4018 Rev.12

Déclaration de Conformité  
Declaration of Conformity

(No.de200220)

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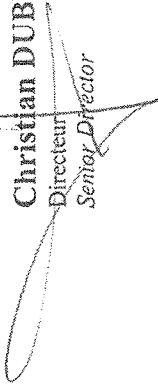
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|                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Catégorie du dispositif<br>Device category | <b>HEMATOLOGY REAGENT</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Nom du produit<br>Product name             | <b>ABX MINOCLAIR (0.5L)</b><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                          | <b>0401005</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 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 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.de 20031v)

Selon  
According to ISO 17050-1

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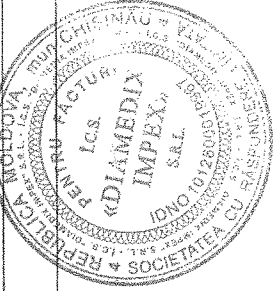
|                                                   |                                                                                                                                                                                                                                                                                                                                                              |
|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Catégorie du dispositif<br><i>Device category</i> | <b>HEMATOLOGY CONTROL</b>                                                                                                                                                                                                                                                                                                                                    |
| Nom du produit<br><i>Product name</i>             | <b>ABX DIFFTROL</b><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><i>Models</i>                          | <b>2062203, 2062207, 2062208,<br/>2062011, 2062012, 2062013</b>                                                                                                                                                                                                                                                                                              |
| Pays d'origine<br><i>Country of origin</i>        | USA                                                                                                                                                                                                                                                                                                                                                          |

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| Normes<br><i>Standards</i>      | N/A                                                                                                                                                                             |

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

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