

Déclaration de Conformité
Declaration of Conformity

(No.de 40013f)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX Pentra ALT CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01627
Pays d'origine <i>Country of origin</i>	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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

Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director

TEMP-4018 Rev.9



Déclaration de Conformité
Declaration of Conformity

(No.de 40015e)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

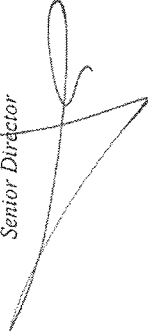
Nom du produit <i>Product name</i>	ABX Pentra AST CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01629
Pays d'origine <i>Country of origin</i>	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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

Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director



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Déclaration de Conformité
Declaration of Conformity

(No. de 40014e)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX Pentra Amylase CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01628
Pays d'origine <i>Country of origin</i>	Germany

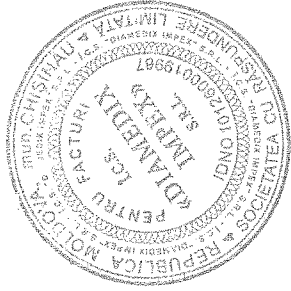
EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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

Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director

TEMP-4018 Rev.9



Déclaration de Conformité
Declaration of Conformity

(No.de 40018e)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

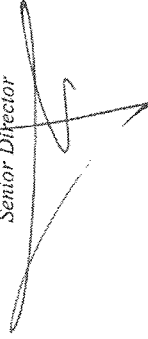
Nom du produit <i>Product name</i>	ABX Pentra CK NAC CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01632
Pays d'origine <i>Country of origin</i>	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

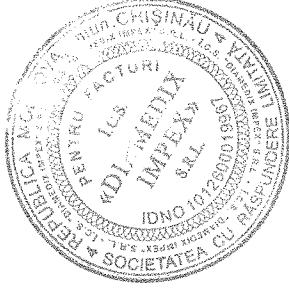
Directives <i>Directives</i>	98/79/EC – IVD Medical Devices Classification : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes <i>Standards</i>	N/A

Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
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Déclaration de Conformité
Declaration of Conformity

(No. de 40027e)

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According to ISO 17050-1

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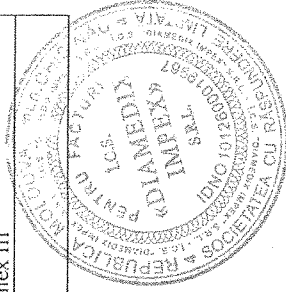
Nom Name	HORIBA ABX SAS
Adresse Address	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit Product name	ABX Pentra BILIRUBIN TOTAL CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles Models	A11A01639
Pays d'origine Country of origin	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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



Montpellier, France
27 janvier 2014
January 27th, 2014

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Déclaration de Conformité
Declaration of Conformity

(No.de 40023d)

Selon
According to ISO 17050-1

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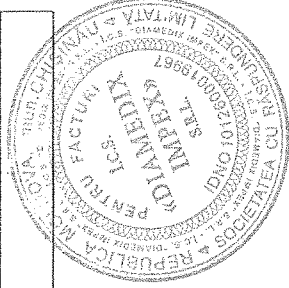
Nom Name	HORIBA ABX SAS
Adresse Address	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit Product name	ABX Pentra BILIRUBIN DIRECT CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles Models	A11A01635
Pays d'origine Country of origin	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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



Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director

TEMP-4018 Rev.9

HORIBA ABX SAS
Parc Euromédécine
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. de 40115d)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

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

Nom du produit <i>Product name</i>	ABX Pentra CALCIUM AS CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01954
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 : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes <i>Standards</i>	N/A

Montpellier, France
27 janvier 2014
January 27th, 2014

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Déclaration de Conformité
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WE THE MANUFACTURER

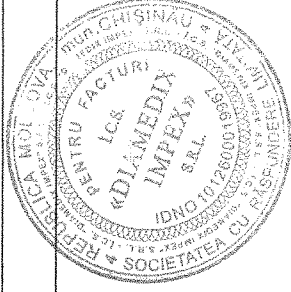
Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 – FRANCE

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX Pentra CK-MB RTU For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01643
Pays d'origine <i>Country of origin</i>	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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



Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director

TEMP-4018 Rev.9

HORIBA ABX SAS

(No. dc 40153b)

Seiorn

WE THE MANUFACTURER

HORIBA ABX SAS

Parc Euromédecine

Parc Euromédecine

34184 MONTPELLIER Cedex 4 - FRANCE

DECLARE THAT THE PRODUCT

ABX Pentra CREATININE 120 CP

C400

A1A01933

France

CONFORMS TO DIRECTIVES AND STANDARDS

98/79/EC – IVD Medical Devices

Classification : Outside Annex II and not for self-testing

Conformity Assessment Procedure: Annex III

Standards

Montpellier, France

27 janvier 2014

January 27th, 2014

Directeur

Senior Director

TEMP-4018 Rev. 9



Déclaration de Conformité
Declaration of Conformity

(No.de 40036e)

Selon
According to ISO 17050-1

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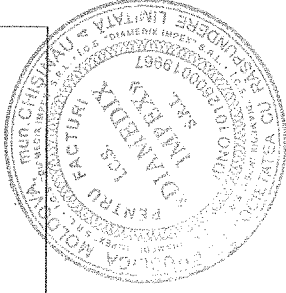
Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX Pentra GLUCOSE PAP CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01668
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 : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes <i>Standards</i>	N/A



Montpellier, France
27 janvier 2014
January 27th, 2014

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Déclaration de Conformité
Declaration of Conformity

(No. de 40113d)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX Pentra LDH CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01824
Pays d'origine <i>Country of origin</i>	Germany

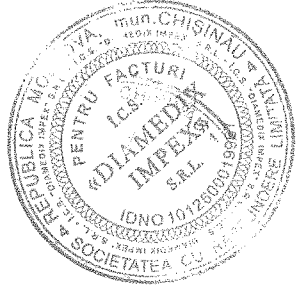
EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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

Montpellier, France
27 janvier 2014
January 27th, 2014

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Directeur
Senior Director

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HORIBA

Déclaration de Conformité
Declaration of Conformity

(No.de 40025e)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

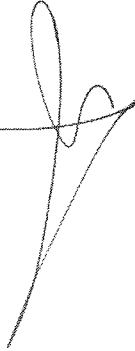
Nom du produit Product name	ABX Pentra IRON CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles Models	A11A01637
Pays d'origine Country of origin	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

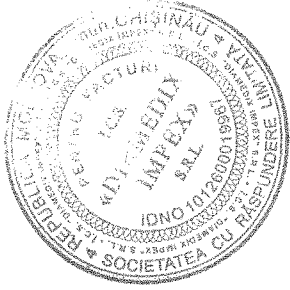
Directives Directives	98/79/EC – IVD Medical Devices Classification : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes Standards	N/A

Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director



TEMP-4018 Rev.9



Déclaration de Conformité
Declaration of Conformity

(No.de 40037e)

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

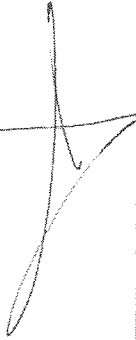
Nom du produit Product name	ABX Pentra TOTAL PROTEIN CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles Models	A11A01669
Pays d'origine Country of origin	France

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

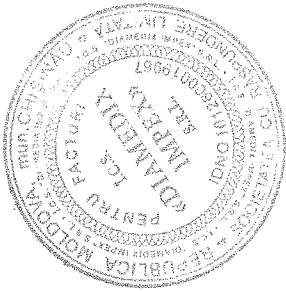
Directives Directives	98/79/EC – IVD Medical Devices Classification : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes Standards	N/A

Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
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HORIBA

Déclaration de Conformité
Declaration of Conformity

(No.de 40029f)

Selon
According to ISO 17050-1

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WE THE MANUFACTURER

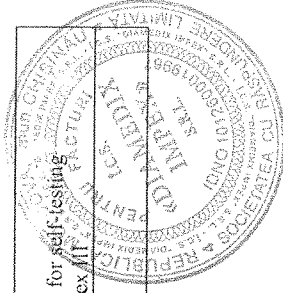
Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX Pentra UREA CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01641
Pays d'origine <i>Country of origin</i>	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

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



Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC

Directeur
Senior Director

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HORIBA

Déclaration de Conformité
Declaration of Conformity

(No.de 40089c)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX Pentra MULTICAL For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01652
Pays d'origine <i>Country of origin</i>	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

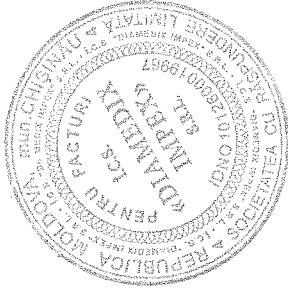
Directives <i>Directives</i>	98/79/EC – IVD Medical Devices Classification : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes <i>Standards</i>	N/A

Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director



TEMP-4018 Rev.9



Déclaration de Conformité
Declaration of Conformity

(No.de 40075d)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

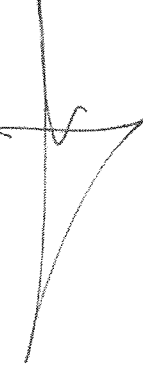
Nom du produit <i>Product name</i>	ABX Pentra FRUCTO CONTROL N For application on : ABX PENTRA 400, PENTRA C400
Modèles <i>Models</i>	A11A01681
Pays d'origine <i>Country of origin</i>	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

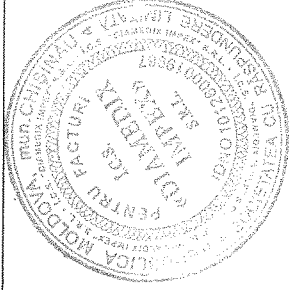
Directives <i>Directives</i>	98/79/EC – IVD Medical Devices Classification : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes <i>Standards</i>	N/A

Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director



TEMP-4018 Rev.9



Déclaration de Conformité
Declaration of Conformity

(No.de 40076d)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX Pentra FRUCTO CONTROL P For application on : ABX PENTRA 400, PENTRA C400
Modèles <i>Models</i>	A11A01682
Pays d'origine <i>Country of origin</i>	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

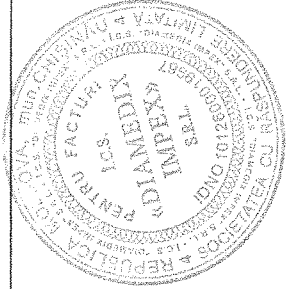
Directives <i>Directives</i>	98/79/EC – IVD Medical Devices Classification : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes <i>Standards</i>	N/A

Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director



TEMP-4018 Rev.9



Déclaration de Conformité
Declaration of Conformity

(No.de 40168a)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

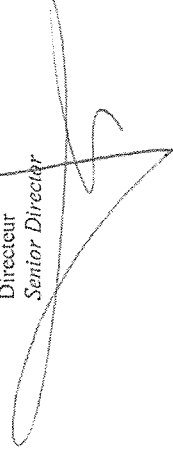
Nom du produit <i>Product name</i>	ABX PENTRA CK 2 CONTROL For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	1300026187
Pays d'origine <i>Country of origin</i>	Germany

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

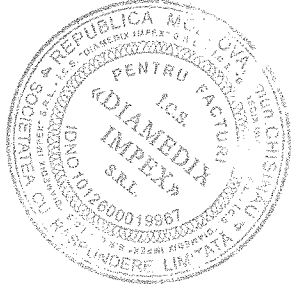
Directives <i>Directives</i>	98/79/EC – IVD Medical Devices Classification : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes <i>Standards</i>	N/A

Montpellier, France
23 Octobre 2016
October 23rd, 2016

Christian DUBUC
Directeur
Senior Director



TEMP-4018 Rev.9



Déclaration de Conformité
Declaration of Conformity

(No.de 40095f)

Selon
According to ISO 17050-1

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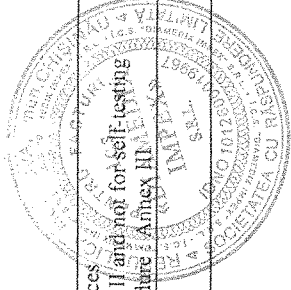
Nom Name	HORIBA ABX SAS
Adresse Address	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit Product name	ABX Pentra CLEAN-CHEM CP ABX Pentra CLEAN-CHEM 99 CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles Models	A11A01755 A11A01789
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 : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex HL
Normes Standards	N/A



Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director

TEMP-4018 Rev.9

Déclaration de Conformité
Declaration of Conformity

(No.de 40096e)

Selon
According to ISO 17050-1

NOUS LE FABRICANT
WE THE MANUFACTURER

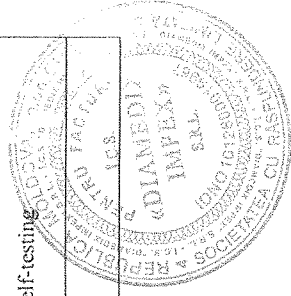
Nom <i>Name</i>	HORIBA ABX SAS
Adresse <i>Address</i>	Parc Euromédecine Rue du Caducée – BP7290 34184 MONTPELLIER Cedex 4 - FRANCE

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom du produit <i>Product name</i>	ABX Pentra DEPROTEINIZER CP For application on : ABX PENTRA 400, PENTRA C200, PENTRA C400
Modèles <i>Models</i>	A11A01754
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 : Outside Annex II and not for self-testing Conformity Assessment Procedure : Annex III
Normes <i>Standards</i>	N/A



Montpellier, France
27 janvier 2014
January 27th, 2014

Christian DUBUC
Directeur
Senior Director

TEMP-4018 Rev.9

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HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée - BP7290
34184 MONTPELLIER Cedex 4 - FRANCE
Web: www.horiba.com
Tel: 33 (0) 4 67 14 15 16

Déclaration de Conformité *Declaration of Conformity*

(No. *dc40106c*)

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

DECLARONS QUE LE PRODUIT
DECLARE THAT THE PRODUCT

Nom produit
Product Name
SAMPLE CUP
For application on: PENTRA 400 and MIRA

Modèles
Models
**A11A01765, A11A01766,
A11A01767, A11A01768**

EST CONFORME AUX DIRECTIVES ET NORMES
CONFORMS TO DIRECTIVES AND STANDARDS

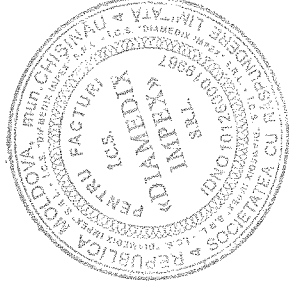
Directives
Directives
98/79/EC - IVD medical devices

Normes
Standards
N/A

Montpellier, France
02 Novembre 2009
November 02nd, 2009

CORP-FORM 0018 Rev.6

Bertrand de CASTELNAU
Directeur Général
General Manager



Bdl

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Web: www.horiba.com
Tel: 33 (0) 4 67 14 1516

(No. dc40137a)

According to ISO 17050-1

WE THE MANUFACTURER

Nom	Name
-----	------

Adresse
Parc Biomédicine

DECLARE THAT THE PRODUCT

Nom produit
Product Name

Modèles
Models

CONFORMS TO DIRECTIVES AND STANDARDS

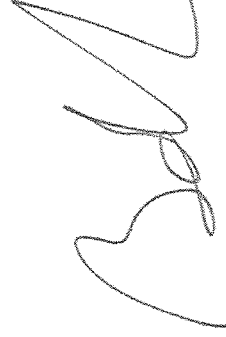
Directives

Normes	Standards
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10 Juillet 2009
July 10th, 2009

Bertrand de C
Directeur Général
General Manager

CORP-FORM 0018 Rev.6



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