

Déclaration de Conformité Declaration of Conformity

(No.de 20032u)

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 |

**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**

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|--|--|
| Catégorie du dispositif Device category | HEMATOLOGY CALIBRATOR |
| Nom du produit Product name | ABX MINOCAL For application on : ABX Micros 45, ABX Micros ABC Vet, ABX Micros 60, ADVIA 60, ABX Micros ES60, ABX Micros ESV60, Scil Vet ABC Plus, ABX Micros CRP, ABX Micros CRP 200, 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, Micros Care ST, Microsemi CRP, Pentra DX Nexus, Pentra DF Nexus, Yumizen H500 OT, Yumizen H500 CT, Yumizen H1500, Yumizen H2500, Yumizen H550 |
| Modèles Models | 2032002 |
| Pays d'origine Country of origin | USA |

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

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|--------------------------|---|
| 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

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