

**HORIBA ABX SAS**

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TO: Agency of Medicine and Medical Devices from Republic of Moldova,  
Registering of Medical Device Department

Montpellier, the 20<sup>th</sup> 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**

**HORIBA**  
Medical

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