**Distributor/Importer Quality Agreement**

**Under In Vitro Diagnostic Medical Device Regulation (EU) 2017/746**

1. **Generalities**
   1. **Scope**

This agreement defines the Quality Agreement between the parties identified below. It defines the commitment both parties make to ensure that their respective products and services satisfy the quality and regulatory requirements called out in this agreement. Both parties agree to cooperate in the success of this agreement.

…

* 1. **Parties to the Agreement**

This Quality Agreement is executed between <Distributor registered name and address> , hereafter referred to as <distributor> and <Manufacturer registered name and address>, hereafter referred to as <Manufacturer >.

* 1. **Definitions**

All relevant definitions specified in…

* 1. **Reference documents**
* …
  1. **Products and Services Covered By This Agreement**

This agreement pertains to the products listed in the table below.

*.*

**2. Compliance with the In Vitro Diagnostic Medical Devices Regulation**

**2.1. Conformity of supplied devices with the Regulation**

The manufacturer undertake to …

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**2.2. Providing copies of CE certificates and Declaration of Conformity**

The manufacturer will provide…

**…**

**2.6 Registration of medical devices and economic operators**

The manufacturer confirms that…

**3. Good distribution Practices**

**3.1 Generalities**

The distributor shall establish…

**3.2 Storage of medical devices**

Medical devices must…

….

**8. Maintaining records**

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