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Quality Policy

(Política de Calidad)

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Manager: Christian Hense

Author: Inmaculada García Pérez	Reviewer: Paola Hurtado Castillo	Approver: Christian Hense
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Change History

Revision	Date	Approval	Changes
001	02/11/2016	ALG, CHE	New document
002	04/05/2018	CHE	Added Multi-“omics” techniques
003	02/08/2019	CHE	Remove references to clinical lab; expand risk management to the different processes of the company.

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Universal Diagnostics S.L. (UDX) is an innovative biomedical start-up specialized in the development of diagnostic tests for the early detection of cancer and precancerous states using multi-“omics” techniques.

Top Management is convinced that the main strategy to win the battle against cancer is its early detection. Therefore, they consider a priority to ensure that research, development, manufacturing and marketing porcesses of IVD medical devices are performed with the greatest efficiency and effectiveness, striving for excellence. Hence, Top Management commits to fulfil the following purposes of quality policy:

- Achieve customers and stakeholders’ (patients, employees, physicians, investors and collaborators) satisfaction, know and meet their expectations as well as respond to their needs.
- Establish a high level of collaboration with suppliers, customers and stakeholders such as investors, collaborators and physicians.
- Increase personal and professional satisfaction, promote teamwork in a suitable environment and enhance training, raising awareness and involving all UDX’s personnel on the continuous improvement of processes and the achievement of objectives.
- Eliminate or minimize the risks associated with the products/services/processes of the Company to provide customers and end users with the maximum level of safety.
- Establish a vigilance system for their own products to detect, classify, record, assess, manage and solve any incident affecting the product on the market.
- Ensure compliance with legal and regulatory requirements applicable to the company, its products and services and compliance with ISO 9001 and ISO 13485 standards.
- Ensure continuous improvement of the Quality Management System (QMS) through the periodic review and adaptation of the objectives, indicators and quality policy to maintain the effectiveness of the QMS and provide the safety and effectiveness of their products.
- Ensure compliance with good professional practice, the performance of appropriate analyses according to their intended use and the continuous improvement of quality.