QUALITY POLICY

We are committed to provide high quality medical diagnostic tests and ultimate services to customers worldwide. We will go further than our competitors to make the difference.

Our ambition is to provide first-in-class diagnostic products for patient health assessment. The values and processes of our organization are fully tuned to optimize products quality. Furthermore, our commercial, technical and scientific teams are attentive to implicit and explicit needs of our current and future customers. We want to excel on customer orientation, flexibility and services.

We have a solid experience for more than 30 years in the development and manufacturing of clinical in-vitro diagnostic products and use the same rigorous and reliable processes for manufacturing and quality control of research products.

On the road to excellence, we do not just guard and assure quality of our products and services, but we promote Continuous Improvement at all levels of the company. As part of that, we also evaluate, challenge and follow up on the quality of the products and services of our suppliers.

In order to design, manufacture and provide compliant, effective and safe products for diagnostic markets worldwide, we maintain a Quality Management System fully in accordance with the following requirements:

- *ISO 9001:2015;*
- *ISO 13485:2016;*
- *IVD Directive 98/79 EC (European Union);*
- *SOR/98-282 (Canada);*
- *21 CFR Part 803, 21 CFR Part 806, 21 CFR Part 807 and 21 CFR Part 820 (US);*
- *TG(MD)R Sch 1 and 3 (Australia);*
- *RDC ANVISA 16/2013, 23/2012, 56/2001 and 67/2009 (Brazil);*
- *MHLW MO169 and 128 (Japan).*

Our Quality Management System is designed to continuously improve customer satisfaction, the quality of our products as well as the effectiveness and the efficiency of our processes. The QMS is reassessed during Management Reviews and Executive Quality Committees (EQC).

To fulfill our commitment to Quality, we are staffed by a competent, professional and continuously trained workforce.

Our objectives for the coming years are to maintain the ISO9001: 2015 certification, to pass the Medical Device Single Audit Program (MDSAP) as well as to comply with the IVD 2017/746.

Established in Louvain-La-Neuve (Belgium) on 09 July 2019.

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