QUALITY AND R&D&I POLICY

TALLADIUM ESPAÑA S.L., hereinafter TLL, is a company committed to the design, manufacture, marketing/distribution, export and import of sanitary products and materials for the dental sector. We establish the following as our main objectives, which are essential for our professional development:

- COMPLIANCE with the legal requirements established in the countries that apply to it, Regulation (EU) 2017/745 of the European Parliament and of the Council, of April 5, 2017, on medical devices, which modifies the Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC . It follows the US FDA regulations, the Australian TGA, the Japanese MHLW and the Canadian HC, of which we are audited in MDSAP (Joint Medical Device Audit Program) annually.
- We continuously REVIEW the legal as well as the regulatory requirements to which our product is submitted assuring their validity and proper compliance.
- That our products comply with the SPECIFICATIONS for which they have been designed and, specially, that they are useful and appropriate according to their PURPOSE of use as stated.
- We listen to the needs and expectations of CUSTOMERS, regarding their management, usefulness and adequacy to the uses which our products can have. We seek to achieve full customer satisfaction by means of products that adjust to their needs and exceed their expectations.
- All products, services and/or activities provided by TLL in relation to the sale, post-sale service, etc. to its customers are PERFORMABLE and efficiently and effectively executed and within the cost margins and terms which meet the needs and/or demands of customers and the expectations of the company.
- Realizamos de forma periódica tareas de análisis, seguimiento y medición de nuestros procesos clave para mantener y MEJORAR los niveles de calidad e I+D+i requeridos por la dirección y PREVENIR de cualquier desviación no deseada.

In order to achieve these goals, TLL maintains a QUALITY and R&D&I Management System in accordance with ISO 9001 and ISO 13485 standards, which ensures the correct operation of the company. Our management system is focused on processes. It establishes and documents the necessary key procedures. It has the necessary means of control to ensure compliance with them in line with the requirements of senior management.

The company applies an R&D&I management system integrated with the quality system in accordance with UNE 166002 in order to guarantee that R&D&I activities meet its expectations and comply with the requirements of the standard. The company is committed to promoting and developing INNOVATIVE and CREATIVE capacity as a key differentiating and fundamental factor to maximise business competitiveness. It is a satisfaction to contribute to the continuous development and improvement of the state of the art by providing innovative solutions. Solutions that help professionals in the dental sector for whom we work and ultimately to improve people's quality of life.

The General Management of TLL declares its firm commitment to the quality management system and R&D&I, which it maintains and periodically reviews, and formally declares it in this POLICY and disseminates it to all the company's personnel.

It also states that the Quality and R&D&I Policy is part of the company's global policy. The general objectives described in TLL's Quality and R&D&I Policy are specified and deployed in specific objectives, which are annually evaluated and approved by the Management, within the Management Committee. The quality and R&D&I policy is reviewed as part of the quality review by management in case any changes or adjustments are necessary.

Lleida, 10-06-2024

Gina Borotau

Quality Manager

Esteban Xam-mar

CEO