QUALITY AND R&D&I POLICY

At TALLADIUM ESPAÑA S.L., hereinafter TLL, we establish as main and essential purposes for our professional development the following:

- 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.

- We analyze the context of our Organization, identify our weak points, threats, strengths and opportunities and we act accordingly.

- We identify, analyze, value and deal with the significant risks of our Organization and processes.

- 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.

- We regularly carry out analysis, follow-up and measurement tasks of our key processes to keep and IMPROVE the quality and R&D&I levels required by the management and TO AVOID any undesired deviation.

In order to achieve such purposes TLL keeps a QUALITY and R&D&I Management System in accordance with rules ISO 9001 and ISO 13485 which gives assurance of the proper operation of the company. Out management system is focused on processes. It sets out and documents the necessary key procedures.

The company applies an R&D&I management system integrated with the quality system according to UNE 166002 with the purpose of guaranteeing that the R&D&I activities meet its expectations and comply with the rule requirements. The company supports the promotion and development of the INNOVATING and CREATIVE capacity as a key differentiating and essential factor to maximize the company competitiveness. It is a satisfaction to contribute in the continuous development and improves the state of art by providing innovating solutions.

The TLL General Management expresses its firm commitment with the quality and R&D&I management system which keeps it and regularly reviews it, as formally declared in this POLICY and it reveals it to all the company staff. Furthermore, it states that the Quality and R&D&I Policy is part of a global policy of the company. The general objectives described within the Quality and R&D&I Policy of TLL are achieved and illustrated in specific objectives, which are annually assessed and approved by the Management, specifically by the board of directors.

Lleida, Jan 14th 2022

Gina Borotau
Quality Manager

Esteban Xam-mar
CEO