



Quality Policy

We aim to manufacture safe and effective medical devices that meet both customer and regulatory requirements. We commit ourselves to comply with regulatory requirements and to maintain the effectiveness of the Quality Management System (QMS). For any process which is outsourced, the methods of control are identified within the QMS.

In case working according to the described processes or procedures would not lead to the desired results, employees are encouraged to issue suggestions for improvement of the quality management system.

To support our policy to implement and maintain an adequate, suitable and effective QMS, we have chosen an external Certification Body for an independent verification of our QMS on a regular basis. The resulting output is an accredited certification, which can be used to demonstrate to the outside world our compliance with specified requirements.

The undersigned herewith declare the application of this manual, and all procedures it refers to, to be mandatory for all employees operating within the defined scope.

A blue ink signature of Max Lousberg, consisting of several loops and a long horizontal stroke.

Max Lousberg
QA Manager
Management Representative

Date: 28-02-2021

A black ink signature of K. Bruinsma, featuring a large, stylized 'B' and 'K'.

K. Bruinsma
CEO

Date: 28-02-2021