

Quality policy



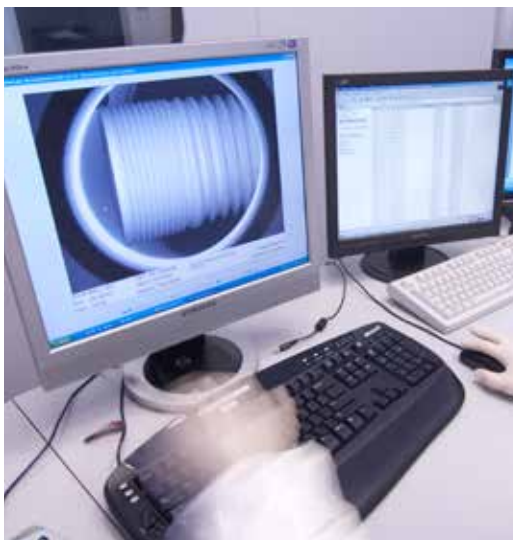
Dear Customer,

We would like to thank for your preference and trust in our products.

We confirm our constant commitment to research and to the quality of our implant systems. The company is certified to ISO 9001 and ISO 13485 and the products are EC certified in compliance with European Medical Device Directive No. 93/42 and subsequent integrations. The company is registered at FDA and in compliance with QSR 820, and the implant systems distributed in America are FDA approved [510(K)].

Sweden & Martina constantly dedicates important resources to Research & Development and to the production of our implant systems:

- a staff of qualified designers assists doctors on a daily basis in their questions and requests,
- we give great importance to the remarks of our users, to their indications and suggestions, which we try to satisfy in a flexible and ergonomic manner,
- we study cutting-edge technological solutions, patented and unique in their kind,
- we continuously evolve our technological and productive department, to maintain the quality of our products at the top of the market,
- we use exclusively the most highly biocompatible raw materials, compliant, tested and certified according to regulations.



The mechanical functionality of the implants is tested in accordance with the applied standards using an FEM structural test (Finite Element Analysis) and with static and dynamic resistance tests. All the systems have been tested to 5,000,000 cycles, to assess their fatigue behaviour, according to standards, and they comply with very strict criteria and parameters of acceptability.



The clinical success of the implants is continuously tested in many clinical and experimental research protocols, carried out by numerous Universities both in Italy and abroad, and by some of the best known research groups in the sector.

These researches are normally published in the most serious and influential journals in the sector, so you can find the abstracts and texts in Medline/Pubmed.

Since some years the company has been regularly publishing the collections of abstracts concerning the most important researches in volumes entitled **"Scientifica - Rassegna Bibliografica - Implantologia"** (Scientific Bibliographic Report of Implantology). The aim of this venture is to spread the clinical knowledge of the most updated protocols concerning the use of Sweden & Martina dental implants. We invite you to ask for a free copy of the available Volumes of "Scientifica" by contacting our Customer Care Office (tel. +39 049.9124300).

On request we will also be pleased to supply you with a complete bibliography, updated in real time, of all the publications available, which today are more than 300.

The average percentage of clinical success and of implant survival demonstrated by the clinical studies on Sweden & Martina dental implants is one of the highest and is in line with the best of those on record for the principal implants on the market. The percentage of osseointegration reported in experimental and histological studies is one of the highest.



Before leaving the factory, all products undergo quality controls even stricter than those required by the standards, to check their conformity and correctness.

The Sweden & Martina warranty policy can be downloaded from the company website. In the event of an ascertained defect, Sweden & Martina recognizes the full product warranty in accordance with the law. Sweden & Martina has stipulated a Product Civil Reliability policy for compensation in the case of ascertained defects that cause damages to patients.

Besides the warranty terms contemplated by the law, if there is a production fault or defect, Sweden & Martina offers free replacement of implant components for 12 years and of ECHO products for 5 years.

Sweden & Martina has always had a FAILED IMPLANT REPLACEMENT policy, which is granted with favourable conditions. This Policy, known as the "Fidelity Service", is listed in the Warranty conditions. The Fidelity option can also be used for the replacement, under favourable conditions, of implants that have expired, or simply been opened by mistake, that have fallen, been handled and then not used, etc. In the case where it is necessary to restock sizes, diameters, lengths, etc., it is also possible to replace NEW IMPLANTS free of charge with others in the same price range, as long as these fixtures are still present in the Sweden & Martina sales programme, and therefore not obsolete, and as long as they are in a sealed pack. Implants bought during particular and identifiable promotional campaigns cannot be replaced.



The doctor provides the patient with a certificate of authenticity and originality of our implant products ("Implant passport") which allows the patient in any part of the world to contact us for spares, assistance and information in the case of need.

Echo individual products are supplied with a declaration certifying the exclusive use of biocompatible materials, of standard components

certified in compliance with European Medical Device Directive No. 93/42 and subsequent integrations, and the adoption of compliant production and control procedures, to satisfy the customers' clinical performance and quality expectations.

Sweden & Martina also guarantees for life the continuity of supply of spare prosthetic components for our implants, even if some fixture lines should be discontinued and/or replaced following new and improved techniques resulting from our experience.



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