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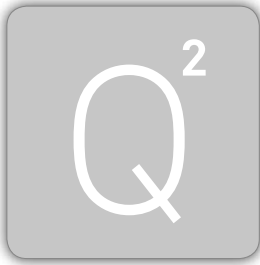
WARRANTY TERMS AND QUALITY POLICY



Warranty terms and conditions for Sweden & Martina implants and standard prosthetic components and for individual Echo prosthetic components.

Foreword

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 boasts ISO 9001:2015 e ISO 13485:2016 certification and its products have EC certification, pursuant to DDM Directive 93/42 and subsequent integrations and European Regulation 2017/745. On the basis of the various markets, many products have obtained local certifications issued by the respective Ministries of Health and competent authorities; for a full and detailed list contact info@sweden-martina.com.

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.



For several years, the company has been regularly publishing collections of abstracts of new publications that refer to Sweden & Martina implants and that become available from time to time in books called Scientifica, Rassegna Bibliografica in Implantologia (Scientifics, Bibliographic Review of Implantology). The first book was published in 2011 and the fifth book went to press in June 2017. 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 customerserviceexport@sweden-martina.com.

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

The average percentage of clinical success and implant survival testified by clinical trials and the percentage of osseointegration shown in experimental and histological studies on Sweden & Martina dental implants are amongst the highest documented in literature.

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

Warranty terms and conditions

Excellent patient care and focus on patient needs are the key to the success of dental implants and it is therefore necessary to carefully select the patient, inform the patient on the inherent risks and duties associated with the treatment and encourage him to cooperate with the dentist, in order to guarantee the success of the treatment itself. It is thus necessary for the patient to maintain good dental hygiene, confirmed during regular check-ups and appointments; good dental hygiene must always be guaranteed and documented and the pre- and post-surgery indications and instructions must also be complied with and documented. Instructions provided by Sweden & Martina are available when treatment begins and are accepted by dental practice; these must be complied with and applied to all treatment phases, from the patient's particular case history through to post-surgery check-ups.



Sweden & Martina guarantees its products against manufacturing faults for the following time period:

- Unlimited lifetime warranty for standard prosthetic implants and components;
- 10-year warranty for individual Echo prosthetic components in countries where these products are offered.

The warranty only covers manufacturing faults that have been confirmed after the piece – identified by an article code and lot number – has been sent for checks within the aforementioned period of warranty validity.

The warranty can be invoked providing the following terms and conditions are complied with:

- The patient must not present any of the contraindications to treatment indicated in the instructions, before, during or after implant surgery.
- Sweden & Martina products must be used in compliance with the indications provided by Sweden & Martina and must not be modified in any way.
- The implant must not be fitted with non-original standard prosthetic components or individual components not produced by Sweden & Martina.
- The implant must not present any damage caused by an accident or trauma or any other damage caused by the patient or third parties.
- Good patient oral hygiene, regularly monitored by the operator and documented.

The warranty provides exclusively for replacement of any product, in which a manufacturing fault has been confirmed, with the same product or a product that is essentially the same.

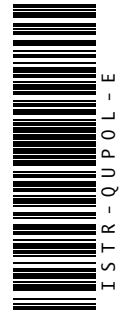
Tailor made training

In order to always keep up-to-date on the most advanced techniques and technologies the global market offers on dental implants, Sweden & Martina organizes a vast range of courses and training events designed to transfer the necessary skills and know-how and to integrate personal dental practice and dental technician practice. Participants will be supervised on their training courses by qualified personnel to support their need, as part of a continual improvement of performances at your service. National and international experts are currently working on the vast program of courses held annually throughout Italy and drafting publications and training materials for implantology techniques, surgical manuals, etc.

We kindly ask you to contact the Training Department on educational@sweden-martina.com or to consult the online calendar of initiatives on www.sweden-martina.com.

For further information, please contact

customerserviceexport@sweden-martina.com



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Sweden & Martina S.p.A.

Via Veneto, 10
35020 Due Carrare (PD), Italy
Tel. +39.049.9124300
Fax +39.049.9124290
info@sweden-martina.com

www.sweden-martina.com

Sweden & Martina Ltd

Unit 45
Basepoint Business Centre
Metcalf Way, Crawley,
West Sussex, RH11 7XX, UK
Toll free 0800 1123575
info.uk@sweden-martina.com

Sweden & Martina Inc.

Distributor for U.S.
80 Broad Street, 5th Floor
New York, Ny 10004
Toll Free: 1-844-8MARTINA (1-844-862-7846)
info.us@sweden-martina.com
www.sweden-martinainc.com

Sweden & Martina Mediterranea S.L. - España

info.es@sweden-martina.com
Sweden & Martina Lda - Portugal
info.pt@sweden-martina.com

The implants, standard prosthetic components and surgical instruments contained in this catalogue are Medical devices and are manufactured by Sweden & Martina S.p.A. They conform to the ISO 9001 and ISO 13485 standards and are certified with the CE Mark (Class I) and CE 0476 mark (Class IIA and class IIB) in compliance with Regulation (EU) Medical Devices n. 2017/ 745.

We have met the good manufacturing standards (GMP) set forth by many countries worldwide, including the United States FDA.

