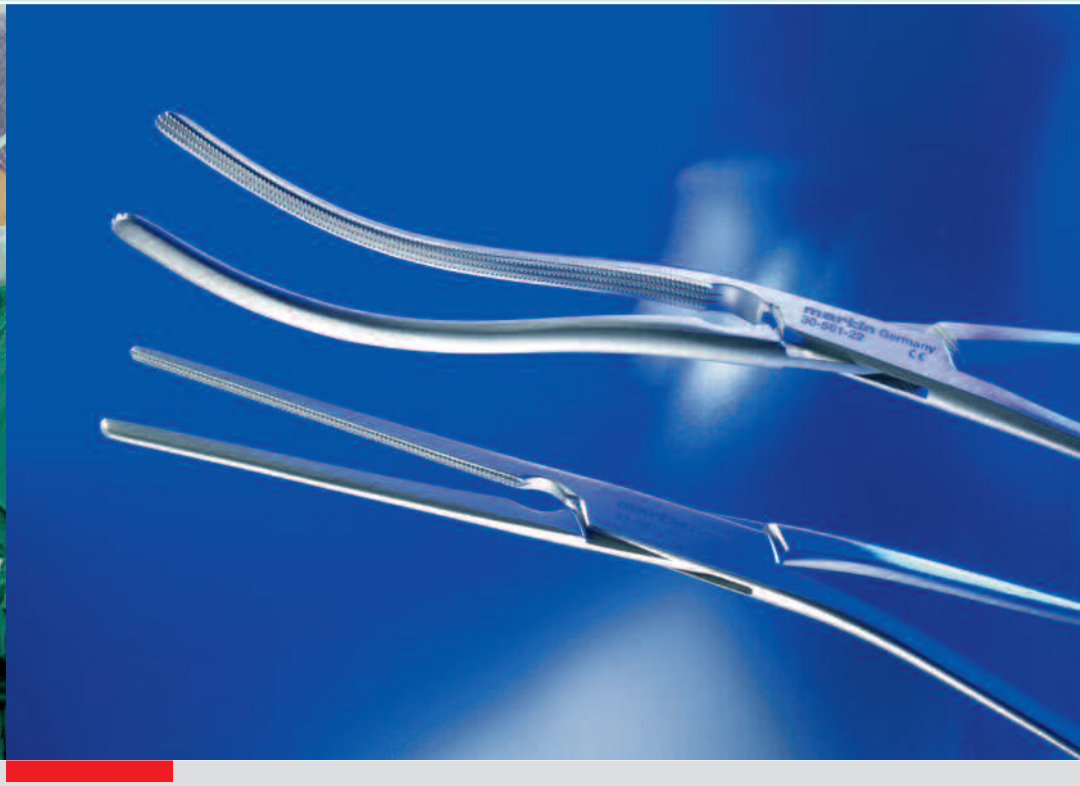
Instruments



KLS Martin Quality Instruments

QUALITY CRITERIA AND REFERENCE STANDARDS

KLS martin GROUP

KLS Martin Quality Instruments

Medical devices are subject to a set of uniform laws throughout the European Union. In this context, the EC Directive concerning medical devices places rigid quality demands on surgical instruments as well. Any manufacturer must heed and meet these requirements, as non-complying products are barred from being placed on the European single market. Similar regulations are in place in the United States and Japan. Other countries have started preparing and implementing their corresponding regulations.

Introduction

As an international supplier of medical devices, Gebrüder Martin GmbH & Co. KG has always given top priority to quality issues with regard to its surgical instruments. In fact, quality was a priority in our company long before legal regulations were put in place. Furthermore, since we have always gone a good deal beyond legal requirements, it is not surprising that competent KLS Martin employees have contributed greatly to the preparation and continuous improvement of both German and international standards governing the function, shape and quality of the various different instruments.

Development

It goes without saying that before an instrument can be manufactured, it must be designed first. The KLS Marin product divisions are, so to speak, the mediators and interpreters between the market and the design engineers. For any new instrument, they identify and define the features and properties desired by the user. In many cases, this involves bringing the development department in contact with leading surgeons, physicians or researchers. This collaboration is frequently reflected in the name given to the new product.

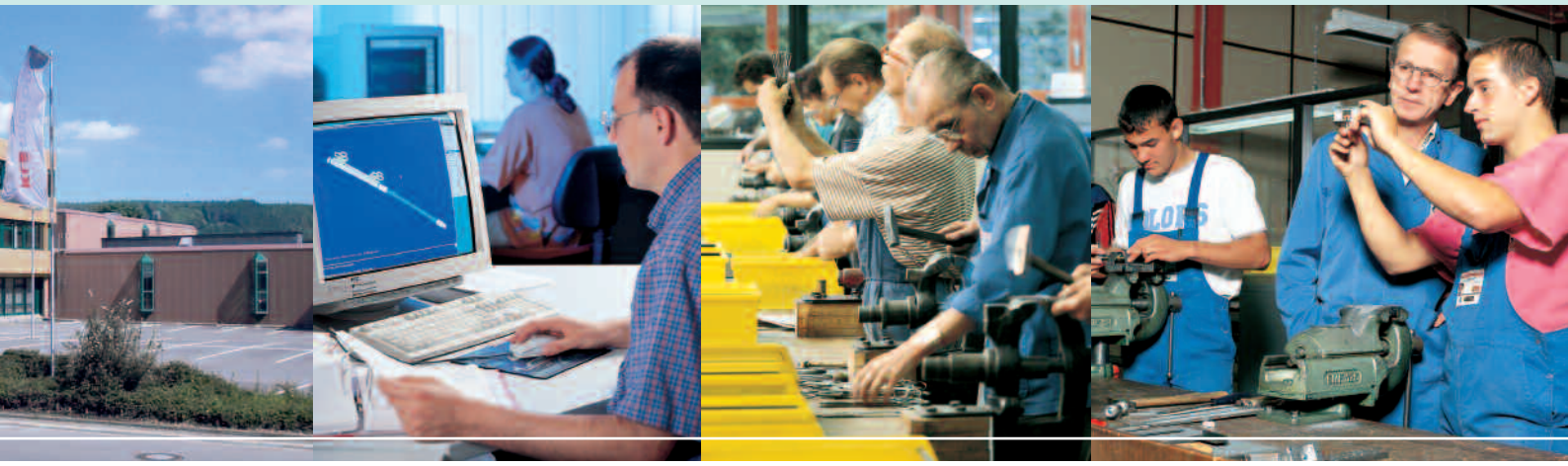
Once the requirements have been established, the design engineers can start developing the new instrument. Where new product series are concerned, we usually make use of our good relationships with leading research and testing institutes. All development efforts, including the tests performed and insights gained, are duly documented in the course of the design and development process. Upon completion of the development phase, the new product is validated against both the requirements defined by the product division and those defined by the law. A declaration of conformity is issued only for products that successfully passed these tests. The design is then released for production.

Materials

The materials used for the manufacture of surgical instruments are nationally and internationally standardized. As most instruments require a high mechanical strength for proper functioning, we are using hardenable chromium steels with a low to medium carbon content. In fact, a chromium content of at least 12.5% is required in order to guarantee sufficient corrosion resistance. As nickel-chromium steels, which have a distinctly higher corrosion resistance, are not heat-treatable, they can only be used for containers, trays and specific large-surface instruments (see Annex “Current reference standards for KLS Martin products“).

Raw Materials

The first step in manufacturing surgical instruments is forging a blank. There are only few certified specialized smithies that are capable of manufacturing such blanks in line with KLS Martin’s specifications regarding the material, shape and dimensions.



Only stainless steel of European origin is used as a source material for manufacturing the blanks. Each steel batch is delivered with a recognized test certificate, and the blanks produced from this source material are likewise duly documented. The quality systems of these contractors have been well aligned with KLS Martin's own quality system. This guarantees that any product can be easily traced to the extent required by the law.

Manufacture

Based on the technical documentation established, the product then enters the manufacturing stage. All manufacturing specifications are subject to quality management. Any changes made on the product can therefore be easily tracked and pinned down at any time.

The manufacturing process is a batch process because the enormous variety of instruments required by our customers does not allow for serial production. This means that almost all instruments are, to a large degree, handmade. Intermediate tests and inspections are clearly defined steps in the process and as such included in the manufacturing documentation.

Heat Treatment

From a functional and reprocessing perspective, the most important step in the manufacturing process is the heat treatment. The heat treatment gives those instruments that are made of hardenable chromium steels the required strength, tenacity and corrosion resistance. In contrast, instruments made of nickel-chromium steels are not hardenable, which means that the use of such steels is limited to special instruments.

In a first step, called "hardening" or "quenching", the instruments are heated to a temperature of more than 1,000°C (1,832°F). At this very high thermal level, the chromium-carbon compounds previously encapsulated in the material dissolve completely, distributing uniformly in the steel. To preserve this ideal structure, the steel is "frozen" by cooling it down fast, which results in a needle-type structure that gives the instrument the strength required for fulfilling its function. At the same time, the uniform distribution of the chromium content enhances the corrosion resistance to such a degree that the instruments are fully corrosion-resistant as long as the user respects the conditions specified for instrument processing.

In a second step, called "tempering", the instruments are kept at a temperature of about 250°C (482°F) for several hours. This treatment reduces the tensions present in the instrument. As a result, the tempered instruments are significantly more elastic and less prone to fractures.

Proper heat treatment is directly reflected in the measured hardness values (see Annex "Current reference standards for KLS Martin products"). Lower (substandard) hardness values indicate insufficient heat treatment and, therefore, a lack of functionality and corrosion resistance.

Function and Finish

Following the heat-treatment stage, specially trained instrument makers give the instruments their final shape, function and finish. Notably, Tuttlingen is the only place in the world with a system of technical colleges and training institutions specially adapted to the needs associated with the manufacture of surgical instruments and medical devices. Highly qualified employees adapt each individual instrument to its intended function. Therefore, most instruments are really “handmade”.

The instruments’ finish has undergone changes lately as a result of more powerful operating lights and video camera systems being used in the OR. In spite of their superior corrosion resistance, mirror-finish instruments are available today only by special order because their light-reflecting surfaces tend to produce an irritating effect during operations. This is why state-of-the-art instruments feature a matte surface today. Whether such non-glare finish is achieved with glass beads or plastic brushes depends on the particular function of the instrument.

Final Inspection and Marking

On its way through the manufacturing cycle, each instrument undergoes a number of specified checks and tests, each of which is duly documented. Nonetheless, KLS Martin also insists on carrying out a classic final inspection. For each instrument, written inspection instructions and an inspection drawing have been put in place, against which every manufacturing batch is carefully checked. This final inspection is also documented in detail. Only those instruments that have passed this final examination are allowed to enter the next stage, where they are marked, cleaned and released for packaging and storage.

By affixing the CE-mark to the product, the manufacturer provides quality assurance. All products carrying this label fully comply with the “essential requirements” specified by the EC Directive concerning medical devices (MDD) as well as with KLS Martin’s documented and validated internal product profiles. As KLS Martin is convinced of the top quality of its surgical instruments, all instruments are covered by a lifetime warranty.

Current Reference Standards for KLS Martin Products

Standard	Content of the standard
DIN EN ISO 9001	**DIN EN ISO 9001,** edition: 2000-12 Quality management systems – Requirements (ISO 9001:2000-09); Trilingual version EN ISO 9001:2000
DIN EN ISO 13485	**DIN EN ISO 13485,** edition: 2003-11 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2003); German version EN ISO 13485:2003
DIN EN ISO 14971	**DIN EN ISO 14971,** edition: 2005-11 Medical devices – Application of risk management to medical devices (ISO/DIS 14971:2005); German version prEN ISO 14971:2005
DIN EN ISO 7153-1	**DIN EN ISO 7153-1,** edition: 2001-02 Surgical instruments – Metallic materials – Part 1: Stainless steel (ISO 7153-1:1991, incl. Amendment 1:1999); German version EN ISO 7153-1:2000
DIN EN ISO 17665-1	**DIN EN ISO 17665-1** Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006); German version EN ISO 17665-1:2006
DIN 50103-3	**DIN 50103-3,** edition: 1995-01 Testing of metallic materials – Rockwell hardness test – Part 3: Modified Rockwell scales Bm and Fm for thin steel sheet
DIN 58298	**DIN 58298,** edition: 2005-12 Medical instruments – Materials, finish and testing
DIN 58299	**DIN 58299,** edition: 1964-01 Serrations for surgical instruments; profile angles, groove distances
DIN 58300	**DIN 58300,** edition: 1982-02 Joints for surgical instruments
DIN EN ISO/IEC 17050-1	**DIN EN ISO/IEC 17050-1:** 2005-01 Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements (ISO/IEC 17050-1:2004); German and English versions EN ISO/IEC 17050-1:2004
DIN EN 60601-1 *VDE 0750-1	**DIN EN 60601-1*VDE 0750-1,** 2004-07 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 62A/449/CDV:2004); German version prEN 60601-1:2004
EN 60601-1	**(Draft standard) DIN EN 60601-1,** edition: 2004-07 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 62A/449/CDV:2004); German version prEN 60601-1:2004
MDD 93/42 Annex II	Medical Device Directive 93/42/EEC; Annex II includes "EC Declaration of Conformity" (full quality assurance)
MDD 93/42, Annex I	Essential requirements, Annex I
DIN EN ISO 17664	**DIN EN ISO 17664,** edition: 2004-07 Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004); German version EN ISO 17664:2004

This information is also available on the Internet at "www.klsmartin.com/Aufbereitung".

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