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Technical Information – Carbon Sterile Surgical Blades – 02 codes

Product Specification

COMPONENT	MATERIAL
BLADE	Carbon Steel **ANALYSIS:** CARBON: 1.2% - 1.3% SILICON: 0.10% - 0.35% MANGANESE: 0.2% - 0.45% CHROMIUM: 0.10% - 0.40% SULPHUR: 0.025% max PHOSPHORUS: 0.035% max
TOP FOIL	Printed Aluminum with Polyethylene
BOTTOM FOIL	Printed Aluminum blade shape with CPP laminate
RUST INHIBITOR	Waxed VCI impregnated kraft paper
UNIT CONTAINER BOX	White lined chipboard with litho machine varnish

Manufacturing information

Details of the manufacturing process and use of associated instructions are described within Process Control Procedure PRO 14.
A brief description of manufacture is as identified below:

Blanking
Stainless or carbon steel strip is fed through a high speed blanking press.

Heat Treatment
This process involves the hardening and tempering of the blade forms.

Breaking off
This operation involves breaking the blank blade forms into individual units ready for edge grinding.

Manufacturing process continued

Inspection
All blanked blades are inspected.

Grinding
The two facets of the edge of each single blade are automatically ground.

Blade Cleaning
All the blades undergo a cleaning operation to remove any traces of extraneous matter.

Blade Inspection
All blades are inspected prior to packing.

In-Process Inspection
All surgical blades are inspected as described in the relevant controlled documents.

Packing and Boxing
Acceptable individual surgical blades are packed in unit containers and subsequently into a shelf box in an environmentally controlled class 8 (5.0 microns ISO 14644) clean room.

Batch manufacturing Record
For control and segregation of production lots see PRO 14 Process Control and INS 14.000 Control and Segregation of Works Orders.

Validation
Process validation is performed in accordance with PRO 9.3 and follows the guidance identified within GHTF Quality Management System – Process Validation Guidance.

Sterilization
Product is sterilized by Gamma Radiation (Cobalt 60) on site by Swann-Morton (Services) Ltd.

The sterilization process is controlled and validated in compliance with the current issue of BS EN ISO 11137-1 Sterilization of healthcare products – Radiation – Part 1 requirements for development, validation & routine control of a sterilization process for medical devices and labelled in accordance with BS EN 556-1 Sterilization of medical devices, requirements for terminally sterilized devices to be labelled sterile.

Standards Employed

The standards employed in the manufacture of sterile surgical blades are: -

BS EN ISO 7153-1
Surgical Instruments – Metallic Materials – Specification for Stainless Steel.

NOTE: The above standard has been withdrawn and replaced by BS EN ISO 7153-1:2016. We still claim compliance with the 2001 version as the composition (Table 1, Letter F) is no longer identified in the 2016 version and we have manufactured stainless steel surgical blades using this composition and marketed them all over the world for over 30 years with no adverse events occurring due to the composition of this stainless steel used.

BS 2982
Materials and packaging of surgical scalpels with detachable blades.

BS EN 27740 / ISO 7740
Instruments for surgery, scalpels with detachable blades, fitting dimensions.

ISO 14644 – 1
Cleanrooms and associated controlled environments.
Part 1: Classification of air cleanliness.

ISO 14644 – 2
Cleanrooms and associated controlled environments.
Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644 – 1.

BS EN ISO 15223-1
Medical devices – Symbols to be used with medical device labels, labeling & information to be supplied.

BS EN 1041
Information supplied by the manufacturer of medical devices.

BS EN ISO 14971
Medical Devices – Application of risk management to medical devices.

BS EN ISO 10993 – 1
Biological evaluation of medical devices.
Part 1: Evaluation and testing.

BS EN ISO 11137 – 1
Sterilization of healthcare products – Radiation
Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

BS EN ISO 11137 – 2
Sterilization of healthcare products – Radiation
Part 2: Establishing the sterilization dose.

BS EN ISO 16061
Instrumentation for use in association with non-active implants – General Requirements.
NOTE:
We have considered and partially comply with this standard and have covered the relevant details within this Technical file.

BS EN 556 – 1
Sterilization of medical devices.
Part 1: Requirements for medical devices to be designated sterile.

BS EN ISO 13485
Medical devices – Quality Management Systems – Requirements for Regulatory Purposes.

93/42/EEC
Council Directive concerning medical devices.

REGULATION (EU) 2017/745
Medical devices

United States Food & Drug Administration
CFR 820 Quality System Regulation

Health Canada
SOR 98/282