MEDICAL DEVICE FILE

For

Speculums

Manufactured by

Gobble Surgical
Sialkot – Pakistan

	Name	Designation	Signature	Date
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01- PRODUCTS COVERED IN THIS MEDICAL DEVICE FILE

Sr. #	Catalog #	Product Description
1.	0103042000	SPECULUM VACHER ENF[AR]
2.	0103043000	SPECULUM DE COLLIN 11MM
3.	0103001000	SPECULUM DE COLLIN 16MM
4.	0103003000	SPECULUM DE COLLIN 25MM
5.	0103006000	SPECULUM DE COLLIN 30MM
6.	0103008000	SPECULUM DE COLLIN 35MM
7.	0103010000	SPECULUM DE COLLIN 38MM
8.	0103011000	SPECULUM DE COLLIN 40MM
9.	0103012000	SPECULUM DE CUSCO 11MM
10.	0103020000	SPECULUM VACHER ENF[AR]
11.	0103023000	SPECULUM DE CUSCO 17MM
12.	0103025000	SPECULUM DE CUSCO 25MM
13.	0103026000	SPECULUM DE CUSCO 27MM
14.	0103027000	SPECULUM DE CUSCO 30MM
15.	0103028000	SPECULUM DE CUSCO 33MM
16.	0103030000	SPECULUM DE CUSCO 38MM
17.	0103031000	SPECULUM DE CUSCO 40MM

02- PURPOSE

The purpose of this Technical File is to provide information to Competent Authorities on the technical documentation needed to meet the requirements of the Medical Device Directive (MDD) 93/42/EEC. This document considers the requirements of technical documentation to satisfy the applicable clauses of ISO 9001:2015, ISO 13485:2016 and Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC.

03- PRODUCT DESCRIPTION

Speculums:

Medical Device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment Or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

As per above definition Speculums are medical devices.

04- INTRODUCTION

A nasal speculum widens the opening of the nose to help the doctor diagnose disease or perform procedures such as: fixing a deviated septum (septoplasty) removing foreign objects from the nose.

05- PRODUCT DESIGN

Design is the creation of a plan or convention for the construction of an object or a system. The design of medical devices represents a synthesis of knowledge and experience gained from any of the specialization areas. Products included in this technical file are well recognized in the international market and well known by the users. These instruments designs were finalized & verified many years ago by competent healthcare professionals and we just manufacture these instruments according to the relevant international standards/Catalogs/customer brochures.

06- MATERIAL SPECIFICATION

These products are made from AISI 304 Stainless Steel Material and their elements composition is as under

Chemical Composition for AISI 304 Material							
ASTM Standard	Carbon	Mn (Max)	P(Max)	Sulfur (Max)	Silicon (Max)	Chromium	Ni (Max)
AISI 304	0.07	2.00	0.045	0.03	1.00	17.00-19.00	8.00-11.00

07- MANUFACTURING & PROCESS FLOW CHART

It is clear from the Technical File that the products are manufactured by Gobble Surgical at their facility in Sialkot, Pakistan. A process flow chart is define below

PROCESS FLOW CHART

1. Raw Material
2. Cutting
3. Die Pressing
4. Forging
5. Machining
6. Filing & Fitting
7. Filing Inspection 100%
8. Electrolyte Polishing
9. QC Inspection 100%
10. Grinding
11. Fitting
12. Rough Polishing
13. Edge Breaking
14. Sand Blast
15. Electrolyte Polishing
16. Passivity & Boil Test
17. Setting
18. Smooth Polishing
19. QC Inspection 4%
20. Ultrasonic Cleaning
21. Final Setting & Functional Test
22. Sand Blasting
23. Re-Polishing
24. Ultrasonic Cleaning
25. QC Inspection 100%
26. Ultrasonic Cleaning
27. Sand Blasting
28. Ultrasonic Cleaning
29. Final Inspection
30. Etching
31. Packing & Labeling
32. QA Inspection 4%
33. Record Review & Release
34. Shipping

08- INTENDED USE OF THE MEDICAL PRODUCT

A nasal speculum widens the opening of the nose to help the doctor diagnose disease or perform procedures

09- Medical Devices Classification

According to Medical Device Directive 93/42/EEC, Annex IX, Rule 5 these reusable Speculums are Class I devices.

10- SAFETY REQUIREMENTS

The products are made of the materials having no cytotoxic, irritant, sensitizing, and toxic effects; they are safe without adverse effects on humans upon use.

11- STORAGE

Store the instruments in a clean and dry environment

12- STERILIZATION

Please see attached Instruction for Use (IFU)

13- TECHNICAL DRAWINGS

Technical drawings give support to the production for developing exact shape of products or other instruments. Production and QA personnel verify product at each production according to drawings. Technical drawing made by technical expert and verified by the Manager QA and Director approves technical drawings. Drawing defines total length & working area sizes etc. Drawings are controlled as per Document & Data Control Procedure.

14- QUALITY CONTROL INSPECTIONS

Receiving Inspection

Receiving Inspection is carried out (as per defined work instructions) to ensure that all material / semi-finished product received; comply with all technical requirements.

In-Process Inspection

In-process inspection is carried (as per defined work instructions) to ensure that the production is proceeding with required specification.

Final Inspection

Final inspection is carried out (as per defined work instructions) before releasing finished product to customers.

15- RISK ANALYSIS

The product must be designed in such a way that it is safe for its intended use. It must be inspected and tested at different stages, made from the appropriate materials, and assembled carefully. Our product's container or packaging is adequate. The Sitec also furnished adequate warnings and directions for use with the product. All designs are over engineered to effectively eliminate any risk to the Surgeon and patient as witnessed by the product specification in general use. Risk Analysis conducted as per ISO 14971:2007.

16- PACKAGING

Polyethylene pouches are used for primary packaging of medical instruments. During packaging we ensure that the pack is large enough to contain the instrument without stressing the seals or tearing the packaging. Cardboard boxes are used for secondary packaging.

17- MARKING & LABELING (WARNING SYMBOLS USED)

Labels or Marking are based as per Gobble Surgical's standard pattern & customer requirements according to their regulatory requirements. Packaging department received information from export department for any modification in labeling or marking listed requirements.

- Customer requirements
- Regulatory requirements
- Country-of-origin requirements
- Traceability/Identification requirements

- Intended Purpose
- Barcode Printing
- European Representative reference
- Logos Mark
- Product Reference
- Product packaging requirements

All changes in labels are documented by QA department of the Gobble Surgical & recorded in packaging department.