



# Certificate of Conformity

Doc #: COC  
Rev: 01

## Certificate of Conformity

This is to certify that the Laryngoscope Blades & Handles manufactured by Gobble Surgical have been produced and tested in accordance with the relevant standards and specifications. The following information confirms the conformity of our products to the required quality and safety standards.

Invoice #: GS/1479/23

Product	Catalog #	Lot #
Mac Intosh LED Laryngoscope Set,3 Blades, N°1,2,3+Handle+Box	DIADEV0013	041223/01
Mac Intosh LED Laryngoscope Set,4 Blades, N°1,2,3,4+Handle+Box	DIADEV0014	041223/02
Miller LED Laryngoscope Set,3 Blades, N°1,2,3+Handle+Box	DIADEV0015	041223/03
Miller LED Laryngoscope Set,4 Blades, N°1,2,3,4+Handle+Box	DIADEV0016	041223/04

## Applicable Standards

ISO 15223-1:2021	Symbols for use in the labeling of medical devices
ISO 14971:2019	Application of risk management to medical devices
ISO 7153-1:2016	Surgical instruments — Materials — Part 1: Metals
ISO 7376:2020	Anaesthetic and respiratory equipment, Laryngoscopes for tracheal intubation

## Material Testing Results

Material Type	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
<b>Result:</b>	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Material Type	CU	Pb	Sn	Zn	Fe (Max)	Ni (Max)	Al (Max)	Si
Brass	65.0-70.0	1.5-3.8	0.50-1.5	24.0-32.0	0.7	1.0	0.35	0.05
<b>Result:</b>	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Sr. #	Product Parameters	Acceptance Criteria	Results
1.	Dimensional Check	As per drawing	Pass
2.	Surface Defect	No consecutive defect on the surface	Pass
3.	Appearance	Surface shall be smooth, no sharpness, burr	Pass
4.	Laser Marking	Shall be legible and as per work instruction	Pass



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Sr. #	Product Parameters	Acceptance Criteria	Results
5.	Labeling	As per Approved Label	Pass
6.	Packaging	As per approved sample	Pass

Note: 100% samples are inspected during Final QC Inspection 100%. Recording of inspection data is done on 4% samples or 4 pieces whichever is higher.

### Compliance Statement:

The Laryngoscope Blades & Handles comply with the applicable regulations and standards for medical devices. The manufacturing processes and quality control measures implemented by our company ensure the reliability and safety of these products.

Prepared & Comparison by: Zeshan Ali (QC Officer)

Approved by: Imran Yousaf (Manager QA)

Date: 09/12/2023