

Certificate



The Governing Board of
Certlink Certification Services
hereby grants to:

F.A. NAJMMY INDUSTRIES

Certificate No: CL/PK/23737-B

(hereinafter called the Registered Company) the right to be listed in the Directory of Registered Companies in respect of the services listed below. These services shall be offered by the Registered Company at or from only the address given below in accordance with the quality management system in Compliance with the Requirements of
ISO:13485:2016.

Address to which this Certificate refers:

136-C Fatima Jinnah Road, S.I.E, Sialkot-Pakistan.

Approved Scope to which this Certificate refers:

**Manufacturers and Exporters of Surgical, Dental, Veterinary,
Beauty Care Instruments & Scissors.**

(Further clarification regarding the Scope of this Certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization)

Signed for and on behalf of the Board

SCHEME MANAGER

Certificate Issue Date: 14 February 2025

Certificate Expiry Date: 13 February 2026

Date of Initial Registration: 13 February 2020

Re-assessment Date: 15 February 2026

This Certificate of Registration is granted subject to the Regulations approved by the Board.

Certlink Certification Services.

Info@cert-link.com
www.cert-link.com



Certificate



The Governing Board of
Certlink Certification Services
hereby grants to:

F.A. NAJMMY INDUSTRIES

Certificate No: CL/PK/23737-A

*(hereinafter called the Registered Company) the right to be listed in the Directory of Registered Companies in respect of the services listed below. These services shall be offered by the Registered Company at or from only the address given below in accordance with the quality management system in Compliance with **ISO:9001:2015**.*

Address to which this Certificate refers:

136-C Fatima Jinnah Road, S.I.E, Sialkot-Pakistan.

Approved Scope to which this Certificate refers:

**Manufacturer and Exporters of Surgical, Dental, Veterinary,
Beauty Care Instruments & Scissors.**

(Further clarification regarding the Scope of this Certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization)

Signed for and on behalf of the Board

SCHEME MANAGER

Certificate Issue Date: 14 February 2025

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NTN: 12566911-2
REX Reg. No: PKREXP125669112

F.A. NAJMMY INDUSTRIES

F.A. NAJMMY INDUSTRIES

Address: 136-C Fatima Jinnah Road Industrial Estate.

Sialkot-51340, Pakistan.

Phone no: 0092 52 3555252

Email ID: najmmy@najmmy.com

We, M/s: F.A. NAJMMY INDUSTRIES under sole responsibility declares that the below mentioned devices have been classified as class-I Surgical and Dental Reusable Instruments. All medical devices according to the classification rules stated in the Annex-IX and conform to the Essential Safety and Performance as laid out in the Annex- I of Council Directive 93/42/EEC as amended by Directive 2007/47/EC for medical devices given in Annex A. The manufactured products meet the essential requirement of Medical Devices Directive 93/42/EEC as amended by 2007/47/EC. We prepare and maintain technical documentation for each device as requires by applicable classification rules and Annex-VII of the directive.

To which this declaration related is in conformity with the following standard(s) or other normative document(s)

ISO 9001:2015	Quality Management Systems
ISO 13485:2016	Medical Devices Quality Managements System – Requirements for Regulatory Purpose
ISO 14971	Medical Devices Application of Risk Management to medical Devices
ISO 17664	Sterilization of Medical Devices – Information to be provided by the manufacturer for the Processing of re-sterilizable medical devices
ISO 15223-1	Medical Devices Symbols to be used with medical device labels, labeling and information to Supplied part-I general requirements.
eGMP	Medical Devices Current Good Manufacturing Practices
ASTM-F899	Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments
ISO 7153-1	Surgical Instruments – Metallic Material – Part 1: Stainless Steel
ISO 21850-1	Dentistry Materials for dental instruments – Part 1: Stainless Steel

Date of issue: 22.09.2023

Authorized Name: Farzand Ali

Signature & Company Stamp

Place of issue: F.A. Najmmy Industries
Sialkot-Pakistan

F.A. NAJMMY Inds



Farzand Ali
Pa n



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NTN: 12566911-2
REF Reg. No: PKREXP125669112

F.A. NAJMMY INDUSTRIES

ANNEX to The Declaration of Conformity

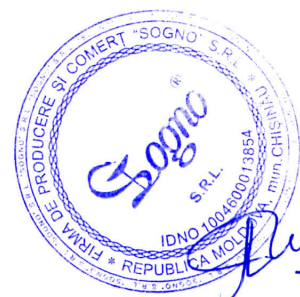
Page (1/1)

Code	Product name	Description	Class	GMDN code
F11-010	Wire saw Olivecrona	L-30cm	I	34821
F11-011	Wire saw Olivecrona	L-40cm	I	34821
F11-012	Wire saw Olivecrona	L-50cm	I	34821
F11-013	Wire saw Olivecrona	L-60cm	I	34821
F11-014	Wire saw Olivecrona	L-70cm	I	34821
F11-015	Wire saw Ggle	6 wirestwisted, L-30cm	I	34821
F11-016	Wire saw Ggle	6 wirestwisted, L-40cm	I	34821
F11-017	Wire saw Ggle	6 wirestwisted, L-50cm	I	34821

F.A. NAJMMY Inds



Ang. Partner



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