



CERTIFICATE # IBC 02105033 This is to certify that

Notrox Instruments

Pura Hiran Nai Abadi Rang Pura, Sialkot-51310-Pakistan

Has been assessed for applicable requirements of Directive 93/42/EEC as updated 2007/47/EC for Class I - Reusable Medical devices (Non-Active/Non-Sterilized/Non-Measuring) and found to meet the requirements of Medical Device Directive satisfactorily and is registered with Sweden Medical Products Agency (Läkemedelsverket) with reference number 6.6.1-2021-37102.

Notrox Instruments comply with the mentioned standards and the status of Sweden's Competent Authority remains legible until compliance and successful surveillance. Manufacturer of a medical device is responsible to meet the applicable requirements in the Medical Devices Act (1993:584) and the Swedish Medicine Agency's Regulations, LVFS 2003:11 or LVFS 2001:7. This assessment exercise was carried with all due care though conformance verification practices and all the regulatory requirement is the sole responsibility of manufacturer.

EU Authorized Representative

IBC - Sweden

Norsborg, Stockholm-Sweden info@ibcsweden.eu

Active Certification:

03-05-2021 to 02-05-2022

First Surveillance:

02-05-2022

Second Surveillance:

01-05-2023

Certification Cycle

Issue Date: 03-05-2021

Expiry Date: 30-04-2024

Remains valid subject to satisfactorily surveillance audit



881014-6707





Part 1/3

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Annex A Authorized Representative Appointment

Part 2/3

The Product Groups mentioned in this annex are included along with variants.

Product Name	Medical Device Classification
Surgical soft-tissue manipulation forceps, alligator, reusable	MDD Class I
Surgical soft-tissue manipulation forceps, scissors-like, reusable	MDD Class I
Surgical soft-tissue manipulation forceps, tweezers-like, reusable	MDD Class I
Instrument Tray	MDD Class I
Amputation knife	MDD Class I
Bandage scissors, reusable	MDD Class I
General-purpose surgical scissors, reusable	MDD Class I
Liposuction cannula, reusable	MDD Class I
Skin marking guide, reusable	MDD Class I
Fibreoptic retractor handle	MDD Class I
Dressing/utility forceps, scissors-like, reusable	MDD Class I
Dressing/utility forceps, tweezers-like, reusable	MDD Class I
Scleral marker, reusable	MDD Class I
Clamp manipulation forceps	MDD Class I
Needle Holder, reusable	MDD Class I
Scalpel handle, reusable	MDD Class I
Scalpel, reusable	MDD Class I
Medicine cup, reusable	MDD Class I
Forceps jar	MDD Class I
Bone file/rasp, manual	MDD Class I
Periodontal file/rasp, manual	MDD Class I
Orthopaedic osteotome	MDD Class I
Orthopaedic chisel	MDD Class I
Hand-held surgical retractor, reusable	MDD Class I
Self-retaining surgical retractor, reusable	MDD Class I

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Annex A

Authorized Representative Appointment

Part 3/3

The Product Groups mentioned in this annex are included along with variants.

Product Name	Medical Device Classification
General-purpose bowl, reusable	MDD Class I
Sterilization/disinfection container	MDD Class I
Surgical mallet	MDD Class I
Mouth gag, adjustable, reusable	MDD Class I
Surgical gouge	MDD Class I
Dental sinus lift elevator	MDD Class I
Periosteal elevator, reusable	MDD Class I
Open-surgery dissector	MDD Class I
Dermatome, manual	MDD Class I
Nasal speculum, reusable	MDD Class I
Eyelid speculum, reusable	MDD Class I
Vaginal speculum, reusable	MDD Class I
Rectal speculum	MDD Class I
Rigid intubation laryngoscope, reusable	MDD Class I
Otoscope, direct	MDD Class I
Direct ophthalmoscope, battery-powered	MDD Class I
Fetal stethoscope	MDD Class I
Cast cutting shears	MDD Class I
Cast/plaster saw	MDD Class I
General-purpose curette	MDD Class I
Orthopaedic joint/limb rongeur	MDD Class I
Surgical hand drill	MDD Class I
Abdominal/intestinal spatula	MDD Class I
Adenoid punch forceps	MDD Class I
Open-surgery biopsy forceps, reusable	MDD Class I

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