USER INSTRUCTION MANUAL.

For Disposable Sterile Metal Instruments

Devices: - PROCEDURE PACKS

Type: - Medical Devices (PACKS OF DIFFERENT INSTRUMENTS HIGHER CLASS APPLICABLE)

Class:-	Rule #:-	Justification
IIA	6	PACKS OF DIFFERENT INSTRUMENTS HIGHER CLASS APPLICABLE

3.1 This is technical documentation number JI/CE/PACKS/A developed, documented and implemented by Jimco Industries, Sialkot, Pakistan as technical . In this documentation efforts have been made to follow the structure/ format recommended for technical documentation by NB-MED/2.5.1/Rec5. The NB-MED/2.5.1/Rec5 is available at http://www.team-nb.org/Documents/R2_5_1-5_rev4.pdf .

3.2. This First Part (A)of the Technical Documentation, consists of a summary of the essential technical data relevant to conformity procedures, including in particular the data listed at NB-MED/2.5.1/Rec5.

3.3. Attention of notified body (reviewing this document) is drawn towards second Note on NB-MED/2.5.1/Rec5.

3.4. This document considers the requirements of technical documentation/ Device Master Record/ Product Specifications to satisfy the applicable requirements of Medical Device Directive number 93/42/EEC as amended up to Directive 2007/47/EC .and the applicable clauses of ISO 13485: 2003, Good Manufacturing Practice (GMP)/Quality System Regulation (QSR) and other applicable international standards.

3.5. The document covers the medical devices packs/ kits enlisted which meet the essential requirement of the above state Directive. These packs do not include any powered/ Active and/or implantable medical devices. The contents (medical instruments) included in these packs/ kits have been selected from the medical instruments covered by our technical file number JI/CE/SDI/A and JI/CE/SDI/B.

3.6. The organization has developed implemented quality management system consistent to the requirements of ISO 9001: 2008, ISO 13485:2003, Annex-II of Medical Device Directive 93/42/EEC, Good Manufacturing Practice (GMP).

APPROVED BY :- Quality Assurance Manager Motasim Umer Nazir- Signature

6.0 Construction/Design

CONSTRUCTION/DESIGN DETAILS OF NON-METAL MEDICAL DEVICES FOR PACKS.

All the metal medical devices included in the packs/ kits covered by this document are the instruments manufactured and packaged under Technical Information/ Specification # JI/CE/SDI/A
Some non-metal medical devices are also included in some of the procedure packs. Their detail with intended use, classification, applicable rules, justification and description is as under

Item # Common / usual name	Size	General Description of the device, material used	Classification & relevant rule			Intended use (brief description of the devices)
			Rule#	Class	Justification	
Sterile crepe sheet	Standard	Single use Sterile Super crepe sheet made of medical grade polyester fabric	1	1	single use non-invasive	Keeps instruments safe from malicious micro-organisiums
UC-1 Clamp	Standard	Single use Umbilical Cold Clamp is Made rom medical grade ABS, Nylon or PE, and POLY	6	11A	Single use Surgically invasive transient use	hold the umbilical cord

The above stated products are purchased in finished form. Upon receipt the above are placed in incoming area where visual inspection of the materials is made and accompanied documents like material report/safety data sheet if applicable, if any are reviewed for verification. In case of approval the material is indicated as approved, batch number is also indicated on the label and shifted to approved material/ in-process store. Results of inspection are recorded on the office copy of relevant purchase order. The rejected materials will be handled according to Control of Non-conforming product Procedure (SOP#10). The Material Data Sheets are part of second Part (B) of Technical File.

In the Clean Room, 100% inspection of the above stated products is made once again and these are included in the relevant procedure packs/ kit alongwith other desired metal medical instruments produced under technical file number JI/CE/SDI/A.

The above products are only included in the following procedure packets/ kits **DA-001-001 /DA-007-001**

In the next sub-sections of this document the relevant packs/ kits compiled out of these medical devices have been identified with their description, sizes, intended use, classification, applicable rule, justification.

4.0 Name and Address of the Manufacturer

4.1. Manufacturer:

Jimco Industries,
4-Km, Aimen Abad Road,
Near Akbar Abad Chowk,
Sialkot, Pakistan

4.2. Authorized Representative : Jimco Healthcare UK, 16 Devonshire Road, Middlesbrough TS5 6DP, London, UK.

5.0 Name and Address of the facilities

5.1 Manufacturer:
(Same as above)

Jimco Industries,

4-Km, Aimen Abad Road,
Near Akbar Abad Chowk,
Sialkot, Pakistan

INSTRUCTION FOR USE

Wear Gloves while using the instruments
The instruments are STERILE unless seal is broken or packaging is damaged. So before using inspect and make sure that the packaging of instruments/ packs is not damaged.
Be careful of the sharp point of the instruments, if any
Be careful of the moving parts of the instruments.
DO NOT TRY TO CLEAN. DO NOT RE-STERILIZE DO NOT RE-USE
Do not use if packaging is damaged
The instruments / packs must be stored in dry place and must be handled with care to prevent damage
Only qualified person should use the healthcare devices. Use only for its intended purpose to ensure maximum effectiveness,
After use the instruments should be disposed off according to local laws

Exception/Exemption:

This document covers single use sterile medical devices/ procedure packs. Although devices of the said classes (Class-I and Class-IIa) are exempted for Instruction for use as mentioned in paragraph 4 of Section 13.1 of Annexure-I of Medical Device Directive 93/42/EEC. The said paragraph of the medical device directive 93/42/EEC is reproduced (pasted) below:

“By way of exception no such instructions for use are needed for devices in Class-I or IIa if they can be used safely without any such instructions.”

We are sure that our these devices can be used safely without such instructions because these are non-powered to be used manually by the trained personnel. Anyway, some brief instructions have been described above in order to facilitate the user. Results of Risk Management of these devices also support our this point of view.

W A R N I N G & P R E C A U T I O N S

WEAR GLOVES WHEN USING THESE INSTRUMENTS FOR PROCEDURAL PURPOSES.
BE CAREFUL TO AVOID INJURY FROM SHARP INSTRUMENT POINTS OR MOVING INSTRUMENT PARTS.THESE INSTRUMENTS SHOULD ONLY BE USED BY QUALIFIED MEDICAL PERSONNEL.
THESE INSTRUMENTS SHOULD ONLY BE USED FOR THEIR INTENDED PURPOSE.
KEEP OUT OF REACH OF CHILDREN

INSTRUCTION FOR PROPER HANDLING OF INSTRUMENTS PACKING AND STERILITY BEFORE USE.

THE INSTRUMENT IN THIS PACK ARE STERILE UNLESS THE SEAL IS BROKEN OR THE PACKAGING IS DAMAGED. INSPECT THAT THE PACKAGING IS UNDAMAGED AND THE SEAL IS UNBROKEN BEFORE USE TO ENSURE STERILITY. HANDLE INSTRUMENTS PACK WITH CARE TO AVOID DAMAGING THE PACKAGING. STORE STERILE INSTRUMENTS PACKS IN DRY PLACE. NORMAL ROOM TEMPERATURE 25 TO 30 °C. BEFORE USE MAKE SURE THE EXPIRE DATE OF THE STERILIZATION . THIS IS A DISPOSABLE PRODUCT, DESIGNED AS A SINGLE USE DEVICE (SUDS).

APPROVED BY :- Quality Assurance Manager Motasim Umer Nazir- Signature