Product Name	Scissors (Non-Sterile and Reusable)
Intended Purpose	A hand-held manual instrument intended to be used to cut bandages and cloth.
Intended User & Patient population	Scissors are used by healthcare professionals including Doctors, Surgeons, Nurses and Paramedics/EMTs. Healthcare professionals should have appropriate knowledge, experience, education, and training to perform pertinent procedure and not by layman to facilitate a procedure. The target patient group includes individuals of all age children, adolescents, adults and elderly (aged 65 and older)**.**
Expected Patient Age Group	All ages children, adolescents, adults and elderly (aged 65 and older)
Indications	Scissors should be used only for the intended purpose for which they are designed. The proper procedure's technique for the use of device(s) is the responsibility of the healthcare professionals including Doctors, Surgeons, Nurses and Paramedics/EMTs.
Contradictions	These devices should not be used with patients, when these are damaged. Moreover, device(s) should not be used for anything other than their intended use.
Diagram /Drawing	Refer to technical drawing, catalogue, etc.
Materials	Stainless Steel used for manufacturing is in conforming ASTM F899-20 and EN ISO 7153-1:2016 respectively, which are recommended for non-active Surgical and Dental Instruments.
Warnings: Solutions, materials, and equipment	
Material and Equipment	• Never use abrasives on device(s), as this will spoil the surface finish. This may later cause discoloration, rusting or pitting. • Do not use abrasive cleaners & brushes. • Use only detergents, cleaning materials and equipment that have been CE marked for processing medical device(s) made from stainless steel.
Warnings: Processing	
Instructions for Use	• When sterilizing Scissors, an autoclave ensures that the instructions from sterilizer's manufacturer are followed. • Always check all instructions for use and sterilization of new device(s).
Temperatures	• No part of the process should exceed 137°C. • The initial cleaning/rinsing should not exceed 40°C.
Personnel	• Always qualified and experienced personnel should perform (re)processing.
Processing	• Do not leave Scissors cleaning or disinfecting solutions for long terms (over night or weekend), the device(s) can be destroyed. • Do not mix Scissors and other materials in the same autoclave load. • All steps of (re)processing must be completed in a sequential manner, moving in one direction only from dirty to clean; as mentioned below.
Handling	• Always handle all device(s) gently. Never overstrain, drop or misuse them. Avoid undue stresses or strains on the device(s) during processing. • Store the device(s) in a clean, cool and dry place. • During transport, cleaning, care, sterilization and storage, all device(s) should be handled with maximum care.
Warnings: Use	
Intended Use	• Ensure Scissors only be used for their intended purpose. • Instrument should always be used in controlled environment i.e., follow the operation theatre SOP/Law.

Before & After use	• An instrument count should be made before and after use to ensure no device(s) are missing. • Check all device(s) for damage before and after use. • Always inspect for rust, pits, crakes, pores, and dents, before and after use.
Limitations on Reprocessing	
End of Life	Due to the product design and the materials used, no definite limit to the maximum number of performable processing cycles can be specified. Repeated processing has minimal effect on these device(s). End of life is normally determined by wear and damage due to use. The service life of the medical device(s) is determined by their function and careful handling. They are then to be disposed of according to best hospital procedure. Do not use any damaged device(s).
Instructions for Reprocessing	
• The device(s) should be monitored, controlled, handled, cleaned and processed by suitably trained and qualified personnel under an approved quality management system such as EN ISO 13485:2016 + A11:2021. • It remains the responsibility of the processor to ensure that the processing as actually performed, using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.	
Preparation at point of use before processing	
Containment & Transportation	• Pack the device(s) in a closed suitable container and transport of the device(s) to the processing location, in order to avoid unwanted movement and damage to device(s) and environmental contamination. • It is recommended that these device(s) are processed as soon as is reasonably practical after use. • Care must be taken to prevent unwanted contamination. Follow the hospital/facility related approved procedures by using trained staff for transporting contaminated device(s).
Preparation at processing facility	
Preparation for Decontamination	No Particular requirements.
Preparing before Cleaning	Ensure staff who will be processing the device(s) are trained.
Manual Cleaning / Disinfection	
Cleaning: Manual	Equipment: Neutral pH Detergent (The ideal cleaning agent is non-abrasive, low-foaming and free-rinsing), CE marked, hospital approved tissue paper, hot air dryer, drying cabinet or air gun. Prepare a cleaning bath according to the manufacturer's instructions. Rinse products with tap water (<40°C) until all visible contamination has been removed. Remove adhering dirt by using a soft brush. Place products in the prepared cleaning bath so that they are completely submersed. Clean the instrument in the bath manually using a soft brush to ensure cleanliness. Rinse the products thoroughly with distilled water to remove the cleaning agents. Always follow best hospital practices / recommended procedures for cleaning and follow detergent manufacturer's instructions for use for the concentration, temperature and contact time. Inspect device(s) for good cleaning result and repeat procedure if necessary. The best effects are achieved by cleaning and rinsing the device(s) immediately after each application.
Disinfection: Manual	Prepare a disinfectant bath and put the instruments in the bath according to the instructions of the disinfectant manufacturer. Rinse the products thoroughly with distilled water to ensure cleanliness.

Manual Drying	Dry the outside of the instruments by carrying out a drying cycle of the cleaning/disinfection machine. If necessary, manual drying may additionally be carried out using a lint-free cloth. Dry cavities by blowing with sterile compressed air.
Automatic Cleaning / Disinfection process	
Automated Cleaning	Cleaning should be performed as soon as possible after use, preferably within one hour of use. Place the instruments in a basket on the insert module or on the inserts of the medical instrument sterilization (MIS) module and start the cleaning process. • Pre-rinse. with cold water for 1 min • Discharge • Pre-rinse with cold water for 3 min. • Discharge • Wash at 55°C with a 0.5% alkaline or at 45°C with an enzymatic cleaning agent for 5 min. • Discharge • Neutralize with warm tap water (>40°C) and a neutralizing agent for 3 min. • Discharge • Rinse with warm tap water (>40°C) for 2 min. • Discharge
Maintenance, inspection and testing	
Packaging	These device(s) should be inspected before and after each use. Visually examine the device(s) for obvious physical damage including: • Cracked, broken or otherwise distorted parts. • Broken or significantly bent device working point. • Damage including cuts, punctures, nicks, abrasion, unusual lumps, significant discoloration. • Tips for damage, corrosion or misalignment condition.
Sterilization	Sterilization of the products with fractional pre-vacuum procedure (in accordance with EN ISO 17665:2024) under observation of the respective national requirements. • 3 pre-vacuum phases with a pressure of at least 60 mbar. • Heating up to a sterilization temperature of at least 134°C and at most 137°C. • Exposure time: at least 3 min. • Drying time: at least 10 min.
Storage	Store packaged device(s) in dry / clean place and dust free environment at moderate conditions as per Hospital best practices to allow device(s) to remain clean, dry, and ready for service.
Stability / Shelf life	5 years
Calibaration	The products do not require calibration.
Disposal	No special decomposition or disposal required for pertinent product(s) as they don't contain any toxic or hazardous material; when recycling medical device(s) please follow your local government Health & Safety procedures and regulatory requirements.
Warranty	This product is guaranteed to be free from defects in material or workmanship. The warranty is void if the product is damaged due to mishandling, misuse, or unauthorized modifications. Care must be taken in the handling and use of this product to maintain warranty rights.
Return	In case of damage or defects, please return the product to the supplier in the original packaging along with a description of the event.
Failed Device(s)	If the device(s) fails any of the quality inspection criteria, it should be segregated, identified accordingly, and decontaminated. It should then either be sent back to the manufacturer for repair with a signed Decontamination Certificate, or disposed of following hospital-approved procedures (e.g., Sharps Bin or Clinical Waste).

Serious Incident	Report any serious incident that has occurred in relation to the device(s) to the manufacturer/authorized representative and the competent authority of the member state where the user and/or patient is established.
Complications	The complications related to the use of the device(s) depend on the procedure adopted; no complications are inherently associated with the device(s).
Legends	
Manufacturer	**Belux Surgical Instruments. (SRN: PK-MF-000042613)** Daska Road Mohabat Khan Pump Station Opposite City Housing, Near Munawar Industry, Sialkot-Pakistan. Phone: +923265452367 Email: info@beluxsurgical.com
EU Authorized Representative	**CMC MEDICAL DEVICES & DRUGS, S.L (SRN: ES-AR-000000293)** C/ Horacio Lengo n18 C. P 29006 Málaga-Spain Phone: +34 951 214 054 Email: info@cmcmedicaldevices.com
Importer	Importer Meher group bv Name:Usman sarwar **SRN:BE-IM-000038305** **Address:Lageweg 213, 2660 Antwerpen , Belgium** **Tel :+32483007131 Email:info@beluxsurgical.com**
CE Marking	The device(s) complies with EU MDR 2017/745 as amended by 2020/561

NON STERILE **Non-Sterile**	MD **Medical Device**	**Keep Dry**

Belux Surgical Instruments Mng Partner

Signature: _____ **Name:** **Mr. Usman Sarwar** **Designation:** **PRRC**