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1. HOW SUPPLIED

Surgical Scissors are supplied in **NON-STERILE condition, intended to be cleaned, disinfected, packaged and sterilized prior to be placed on market or use**. Surgical Scissors are intended for Single Use only.

2. DESCRIPTION

The Non-Sterile, Single Use Surgical Scissors are hand-held, manual cutting instruments designed to cut biological tissues, sutures, and surgical materials during medical procedures by surgical professionals who have knowledge of the instrument features and their proper use. They are precision-engineered for controlled shearing action, providing clean and accurate cuts with minimal tissue trauma.

Surgical Scissors are made of medical grade stainless-steel in compliance with EN ISO 7153-1:2016. Surgical Scissors are designed to perform their function in compliance with ISO 7151:2024. Surgical Scissors are safe from corrosion in compliance with EN ISO 13402:2000.

Instructions are intended for use only by persons with specialized training in the use of surgical instruments. **SEE LABEL ON PACKAGE FOR TECHNICAL DESCRIPTION (NON-STERILE, SINGLE USE, DESCRIPTION OF INSTRUMENT, SHAPE CHARACTERISTICS & DIMENSIONAL CHARACTERISTICS) OF THE PACKAGE CONTENT.**

3. INTENDED PURPOSE / USE

Surgical Scissors are designed for use by surgical professionals who have knowledge of the instrument features and related surgical techniques of **precise cutting of tissues, vessels and various materials during surgical procedures**. Selection of Surgical Scissors type, model & size are at the discretion of the QUALIFIED SURGEON / PARAMEDICAL STAFF based on the most suitable Surgical Scissors for the SURGICAL TECHNIQUE being performed and based on his/her EXPERTISE and MEDICAL TRAINING. Surgical Scissors are used in a medical setting determined by the medical professionals. Surgical Scissors are used primarily to facilitate the surgical treatment, mitigation, prevention, and/or diagnosis of surgical diseases or conditions.

3.1 INTENDED PURPOSE / USE OF 12 VARIANTS:

Variant – T101: Non-Sterile, Single Use, Surgical Scissors: (GMDN: 58949 General-purpose surgical scissors, single-use) Instruments designed to cut objects, materials, and/or tissues using two metallic (stainless steel) blades with sharp edges that slide past each other (shearing action).

Variant – T102 Non-Sterile, Single Use, Surgical Scissors, Nasal: (GMDN: 13495 Nasal scissors) Surgical Scissors designed to cut hard nasal (bony, cartilage) tissue during plastic and/or reconstructive procedures.

Variant – T103 Non-Sterile, Single Use, Surgical Scissors, Scissors, Surgical Suture / Stitch Removal: (GMDN: 63487 Suture cutter, single-use) Surgical Scissors designed to cut sutures and/or to remove stitches.

Variant – T104 Non-Sterile, Single Use, Scissors, Dental / Oral Surgery, Gum / Soft Oral Tissue: (GMDN: 31822 Dental surgical scissors) Surgical Scissors designed to cut and/or trim the gums and/or other soft tissue in the oral cavity during dental and/or oral surgery.

Variant – T105 Non-Sterile, Single Use, Scissors, Surgical, Abdominal / Thoracic Cavity Tissue Dissection: (GMDN: 58949 General-purpose surgical scissors, single-use) Surgical Scissors designed for dissection of soft tissue in deep surgery procedures performed in the abdominal and/or thoracic cavities.

Variant – T106 Non-Sterile, Single Use, Scissors, Surgical, Intestine: (GMDN: 58949 General-purpose surgical scissors, single-use) Surgical Scissors designed to cut tissue from the intestine (bowels).

Variant – T107 Non-Sterile, Single Use, Scissors, Surgical, Uterine: (GMDN: 64045 Gynecological scissors, single-use) Surgical Scissors designed to cut and dissect tissues in the uterus and surrounding tissues.

Variant – T108 Non-Sterile, Single Use, Scissors, Surgical, Uterine, Fetal Decapitation: (GMDN: 64045 Gynecological scissors, single-use) Surgical Scissors designed for fetal decapitation.

Variant – T109 Non-Sterile, Single Use, Scissors, Surgical, Episiotomy: (GMDN: 64045 Gynecological scissors, single-use) Surgical Scissors designed to perform an incision in the peritoneum and vagina during labor (episiotomy).

Variant – T110 Non-Sterile, Single Use, Scissors, Surgical, Vascular: (GMDN: 44354 Vascular scissors) Surgical Scissors designed to cut and/or dissect blood vessel (vascular) tissues.

Variant – T111 Non-Sterile, Single Use, Scissors, Surgical, Wire Cutting: (GMDN: 63487 Suture cutter, single-use) Surgical scissors designed to cut small-caliber suturing wires.

Variant – T112 Non-Sterile, Single Use, Scissors, Umbilical Cord: (GMDN: 64021 Umbilical cord scissors, single-use) Scissors designed to use in labor (obstetric) procedures to cut the umbilical cord after the cord is appropriately clamped.

3.2 INDICATION FOR USE OF 12 VARIANTS:

Variant – T101: Non-Sterile, Single Use, Surgical Scissors: (GMDN: 58949 General-purpose surgical scissors, single-use) Indicated for cutting soft tissues, sutures, and dressings during general surgical and clinical procedures. Suitable for use in minor, major, and outpatient surgeries. Not intended for bone or cartilage cutting.

Variant – T102 Non-Sterile, Single Use, Surgical Scissors, Nasal: (GMDN: 13495 Nasal scissors) Indicated for cutting or reshaping nasal cartilage and soft bone during rhinoplasty or nasal reconstructive surgery. Used by ENT or plastic surgeons for precise trimming of nasal structures.

Variant – T103 Non-Sterile, Single Use, Surgical Scissors, Scissors, Surgical Suture / Stitch Removal: (GMDN: 63487 Suture cutter, single-use) Indicated for cutting and removing non-absorbable sutures or stitches after wound healing. Suitable for use in general surgery, dermatology, and outpatient care.

Variant – T104 Non-Sterile, Single Use, Scissors, Dental / Oral Surgery, Gum / Soft Oral Tissue: (GMDN: 31822 Dental surgical scissors) Indicated for cutting or trimming gingival and other soft oral tissues during dental and oral surgical procedures. Used in periodontal and minor oral surgeries.

Variant – T105 Non-Sterile, Single Use, Scissors, Surgical, Abdominal / Thoracic Cavity Tissue Dissection: (GMDN: 58949 General-purpose surgical scissors, single-use) Indicated for dissection and cutting of soft tissues during open or minimally invasive abdominal or thoracic surgeries. Suitable for general, gastrointestinal, and cardiothoracic surgical use.

Variant – T106 Non-Sterile, Single Use, Scissors, Surgical, Intestine: (GMDN: 58949 General-purpose surgical scissors, single-use) Indicated for cutting and dissecting intestinal or bowel tissues during gastrointestinal surgery. Used in procedures involving resection or anastomosis of the intestines.

Variant – T107 Non-Sterile, Single Use, Scissors, Surgical, Uterine: (GMDN: 64045 Gynecological scissors, single-use) Indicated for

cutting and dissecting uterine or surrounding soft tissues during gynecological surgeries such as myomectomy, hysterectomy, or D&C procedures.

Variant – T108 Non-Sterile, Single Use, Scissors, Surgical, Uterine, Fetal Decapitation: (GMDN: 64045 Gynecological scissors, single-use) Indicated for fetal decapitation procedures during obstetric interventions where medically justified. Intended for use by trained obstetric or gynecologic professionals in controlled surgical settings.

Variant – T109 Non-Sterile, Single Use, Scissors, Surgical, Episiotomy: (GMDN: 64045 Gynecological scissors, single-use) Indicated for performing incisions in the perineum and vaginal wall (episiotomy) during childbirth to facilitate delivery and prevent uncontrolled tearing. Used by obstetric professionals.

Variant – T110 Non-Sterile, Single Use, Scissors, Surgical, Vascular: (GMDN: 44354 Vascular scissors) Indicated for cutting and dissecting blood vessels during vascular or cardiovascular surgeries. Suitable for creating vessel openings or removing vascular tissue with precision.

Variant – T111 Non-Sterile, Single Use, Scissors, Surgical, Wire Cutting: (GMDN: 63487 Suture cutter, single-use) Indicated for cutting small-caliber suturing or fixation wires during orthopedic, dental, or general surgical procedures. Designed for use on metallic or stainless-steel wires.

Variant – T112 Non-Sterile, Single Use, Scissors, Umbilical Cord: (GMDN: 64021 Umbilical cord scissors, single-use) Indicated for cutting the umbilical cord after delivery once clamped. Used in obstetric and neonatal care settings by trained healthcare professionals.

3.3 INTENDED USERS OF 12 VARIANTS:

Variant – T101: Non-Sterile, Single Use, Surgical Scissors: (GMDN: 58949 General-purpose surgical scissors, single-use): Qualified surgeons, physicians, and healthcare professionals trained in general surgical procedures.

Variant – T102 Non-Sterile, Single Use, Surgical Scissors, Nasal: (GMDN: 13495 Nasal scissors) ENT surgeons and plastic/reconstructive surgeons trained in nasal surgeries.

Variant – T103 Non-Sterile, Single Use, Surgical Scissors, Scissors, Surgical Suture / Stitch Removal: (GMDN: 63487 Suture cutter, single-use) Surgeons, physicians, nurses, and other trained medical staff performing suture or stitch removal.

Variant – T104 Non-Sterile, Single Use, Scissors, Dental / Oral Surgery, Gum / Soft Oral Tissue: (GMDN: 31822 Dental surgical scissors) Dentists, oral surgeons, and periodontists trained in oral and maxillofacial surgical procedures.

Variant – T105 Non-Sterile, Single Use, Scissors, Surgical, Abdominal / Thoracic Cavity Tissue Dissection: (GMDN: 58949 General-purpose surgical scissors, single-use) General surgeons, gastrointestinal surgeons, and thoracic surgeons trained in abdominal and thoracic surgical techniques.

Variant – T106 Non-Sterile, Single Use, Scissors, Surgical, Intestine: (GMDN: 58949 General-purpose surgical scissors, single-use) Gastrointestinal and general surgeons trained in intestinal and bowel surgery.

Variant – T107 Non-Sterile, Single Use, Scissors, Surgical, Uterine: (GMDN: 64045 Gynecological scissors, single-use) Gynecologists and obstetric surgeons trained in uterine and pelvic surgeries.

Variant – T108 Non-Sterile, Single Use, Scissors, Surgical, Uterine, Fetal Decapitation: (GMDN: 64045 Gynecological scissors, single-use) Obstetric and gynecologic surgeons trained in specialized obstetric interventions under medically justified conditions.

Variant – T109 Non-Sterile, Single Use, Scissors, Surgical, Episiotomy: (GMDN: 64045 Gynecological scissors, single-use) Obstetricians and midwives trained in performing episiotomies during childbirth.

Variant – T110 Non-Sterile, Single Use, Scissors, Surgical, Vascular: (GMDN: 44354 Vascular scissors) Vascular and cardiovascular surgeons trained in microsurgical or vascular procedures.

Variant – T111 Non-Sterile, Single Use, Scissors, Surgical, Wire Cutting: (GMDN: 63487 Suture cutter, single-use) Surgeons, orthopedic specialists, and dental professionals trained in procedures involving surgical or fixation wires.

Variant – T112 Non-Sterile, Single Use, Scissors, Umbilical Cord: (GMDN: 64021 Umbilical cord scissors, single-use) Obstetricians, midwives, and trained healthcare staff involved in childbirth and neonatal care.

3.4 INTENDED PATIENT POPULATION FOR 12 VARIANTS:

Variant – T101: Non-Sterile, Single Use, Surgical Scissors: (GMDN: 58949 General-purpose surgical scissors, single-use): Patients undergoing surgical or clinical procedures requiring cutting of soft tissue, sutures, or dressings.

Variant – T102 Non-Sterile, Single Use, Surgical Scissors, Nasal: (GMDN: 13495 Nasal scissors) Patients requiring nasal reconstruction, correction of nasal deformities, or tissue reshaping in rhinoplasty procedures.

Variant – T103 Non-Sterile, Single Use, Surgical Scissors, Scissors, Surgical Suture / Stitch Removal: (GMDN: 63487 Suture cutter, single-use) Patients who have previously undergone surgical or wound-closure procedures and require removal of non-absorbable sutures or stitches.

Variant – T104 Non-Sterile, Single Use, Scissors, Dental / Oral Surgery, Gum / Soft Oral Tissue: (GMDN: 31822 Dental surgical scissors) Patients undergoing dental or oral surgeries requiring trimming or cutting of gingival or soft oral tissues.

Variant – T105 Non-Sterile, Single Use, Scissors, Surgical, Abdominal / Thoracic Cavity Tissue Dissection: (GMDN: 58949 General-purpose surgical scissors, single-use) Patients undergoing open or minimally

invasive abdominal or thoracic procedures involving soft-tissue dissection.

Variant – T106 Non-Sterile, Single Use, Scissors, Surgical, Intestine: (GMDN: 58949 General-purpose surgical scissors, single-use) Patients undergoing surgical procedures involving the intestines, including bowel resection, repair, or anastomosis.

Variant – T107 Non-Sterile, Single Use, Scissors, Surgical, Uterine: (GMDN: 64045 Gynecological scissors, single-use) Female patients requiring surgical procedures involving the uterus or surrounding reproductive tissues.

Variant – T108 Non-Sterile, Single Use, Scissors, Surgical, Uterine, Fetal Decapitation: (GMDN: 64045 Gynecological scissors, single-use) Female patients in obstetric cases requiring fetal decapitation as part of a controlled medical or surgical procedure.

Variant – T109 Non-Sterile, Single Use, Scissors, Surgical, Episiotomy: (GMDN: 64045 Gynecological scissors, single-use) Female patients in labor where a controlled incision in the perineum and vaginal wall is required to assist delivery.

Variant – T110 Non-Sterile, Single Use, Scissors, Surgical, Vascular: (GMDN: 44354 Vascular scissors) Patients undergoing surgical procedures involving blood vessels, vascular repair, or vessel dissection.

Variant – T111 Non-Sterile, Single Use, Scissors, Surgical, Wire Cutting: (GMDN: 63487 Suture cutter, single-use) Patients undergoing orthopedic, dental, or general surgical procedures requiring cutting or adjustment of metal suturing or fixation wires.

Variant – T112 Non-Sterile, Single Use, Scissors, Umbilical Cord: (GMDN: 64021 Umbilical cord scissors, single-use) Newborn infants whose umbilical cord requires cutting after safe clamping during delivery.

4. USE WITH OTHER DEVICES OR EQUIPMENT

Surgical Scissors are designed to perform their intended function alone without combination of other devices or equipment.

5. LIMITATION OF LIFE / SHELF-LIFE / STERILITY

Surgical Scissors are intended for SINGLE USE Only. Shelf-Life is claimed as 3 years.

6. INDICATIONS & CLINICAL BENEFITS

Surgical scissors are medical instruments intended for cutting, dissecting, or trimming tissues and materials during surgical procedures. Their specific indications include:

1. Soft tissue dissection – e.g., skin, fascia, muscle.
2. Cutting sutures – during or after closure of surgical wounds.
3. Sharp dissection – of delicate anatomical structures.
4. Blunt dissection – using blunt-tipped scissors to separate tissues without cutting.
5. Trimming and shaping – tissues, grafts, or prosthetics.

6. Opening incisions or cavities – in general, orthopaedic, gynaecologic, ophthalmic, ENT, and other surgical specialties.
7. Use in minimally invasive surgery – when configured as laparoscopic scissors.

7. CONTRAINDICATIONS, UNDESIRABLE SIDE EFFECTS & PATIENT TARGET GROUP

As determined by the QUALIFIED SURGEON / PARAMEDICAL STAFF performing the related surgical intervention, including information to be conveyed to the patient in this regard.

8. PERFORMANCE & SAFETY CHARACTERISTICS

Surgical Scissors fulfil PERFORMANCE requirements in compliance with harmonized standards EN ISO 7741, EN ISO 7153-1 and EN 10088-1 respectively. Surgical Scissors fulfil SAFETY requirements in compliance with harmonized standard BS EN ISO 13402 for resistance against autoclaving, corrosion, and thermal exposure.

9. USE INSTRUCTIONS / TREATMENT BEFORE DEVICE IS READY FOR USE

Weldon Instruments is supplying **NON-STERILE, Single Use, Surgical Scissors to Customer / Importer (procedure pack / instrument kit manufacturers)**. Customers are responsible to shall physically inspect Surgical Scissors thoroughly upon receipt of shipment. Surgical Scissors shall be:

Cleaned & disinfected using validated process in compliance with GHTF/SG3/N99-10:2004 (Edition 2) Quality Management Systems - Process Validation Guidance, ISO 15883-1:2021 Washer-disinfectors — Part 1: General requirements, definitions, and tests, ISO 15883-2:2006 Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices, ISO 15883-5:2021 Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy, ISO 15883-7:2021 Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment, ISO 13485:2016 — Clause 7.5.6 Process validation for production and service provision.

Packaged using validated process in compliance with GHTF/SG3/N99-10:2004 (Edition 2) Quality Management Systems - Process Validation Guidance, EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems, EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes, ISO/TS 16775:2021 Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2, ISO 13485:2016 — Clause 7.5.6 Process validation for

production and service provision, ASTM F88 / F1929 / F2096 / F1980 Test Methods for Seal Strength, Dye-Penetration, Bubble Leak, and Accelerated Aging.

Sterilized (Sterility Assurance Level SAL 10^{-6}) using validated process in compliance with GHTF/SG3/N99-10:2004 (Edition 2) Quality Management Systems - Process Validation Guidance, EN ISO 11135:2014/A1:2019 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices, EN ISO 11737-1:2018/A1:2021 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products, EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process, ISO 10993-7:2008 Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals, **prior to place on market or in use.**

Prior to use of any single use instrument, remove any protective tips or coverings and perform a visual inspection and functional evaluation, especially focusing on tips, teeth, blades, hollow areas, and moveable parts. Ensure no instruments have breaks, cracks, bends, or any other defects of malfunctions prior to use.

10. POTENTIAL COMPLICATIONS

Potential complications are dependent on the disease being treated, techniques used by the medical professional, proper use of the instruments, and the suitability of the instrument used relative to the disease being treated.

11. DEVICE WITH MEASURING FUNCTION

Measuring function is not claimed for Surgical Scissors

12. PRECAUTIONS

Risks associated with surgical instruments include improper use or technique by an operator and transmitting infection or disease due to improper handling techniques. Improperly handled instruments may contribute to postoperative infections. Single use instruments if reused, may not function as intended and may pose risk of injury or disease to patient, user, or other medical staff.

13. WARNINGS

- ⚠ Consult instructions for use (IFU) prior to use.
- ⚠ Do not use after expiry date.
- ⚠ Keep dry, storage in moist / humid environment may cause rusting of instruments.
- ⚠ Keep away from sunlight.
- ⚠ Fragile, handle with care
- ⚠ The instruments are delivered in non-sterile condition and intended to be cleaned, disinfected, packaged and sterilized

prior to be placed on market or use.

- ⚠ Surgical Scissors are intended for single use only.
- ⚠ Before using, examine the instruments. Do not use instruments that show problems or defects.
- ⚠ Remove the plastic protective cap from the instrument before use.
- ⚠ During use, if you observe malfunction of instrument or changes in its performance that may affect safety, please STOP use of instrument and report to Hasa Optix.
- ⚠ Do not reuse, reuse may result in infection or injury.
- ⚠ Do not reprocess or re-sterilize the instruments.
- ⚠ Instruments must be used for their specified purpose; incorrect use may damage the instrument or may cause injury to patient, user, or other medical staff.
- ⚠ Surgical Scissors are made of stainless steel (metal). The accuracy of electromagnetic navigation systems may be affected substantially by the size, type, proximity, and shape of metal object.

14. STORAGE

Before use, store the sterile instruments at ambient conditions in dry place away from sunlight in a manner that protects the device and reduces the possibility of contamination. Instruments are fragile, handle with care.

15. DISPOSAL

After use, sharp instruments should be disposed of in a sharp's disposal container. All used instruments having potentially infectious substances from human origin, should be disposed of in a biomedical waste stream in compliance with hospital's waste management program & local regulatory requirements. Packaging may be disposed of in normal waste streams with no additional precautions.

16. QUALITY STANDARDS

WELDON INSTRUMENTS is committed to providing the highest quality Surgical Scissors. **WELDON INSTRUMENTS** maintains a Quality Management System in compliance with EN ISO 13485, Medical Device Directive 93/42/EEC & Regulation (EU) 2017/745 requirements.

17. WARRANTY

WELDON INSTRUMENTS warrants that this medical device is free from defects in both materials and workmanship. **ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.** Suitability for use of this medical device for any specific surgical procedure should be determined by the user in conformance with the best knowledge of surgical surgery

techniques. **THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF.**

18. IMPORTANT NOTICE TO USER

ANY SERIOUS INCIDENT THAT HAS OCCURRED IN RELATION TO SURGICAL SCISSORS SHALL BE REPORTED TO THE MANUFACTURER (WELDON INSTRUMENTS) AND THE CONCERNED COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND/OR PATIENT IS ESTABLISHED.

19. CONTACT FOR TECHNICAL ASSISTANCE

Tel: +92 300 8713001

E-mail: junaid@weldoninstruments.com

20. MANUFACTURER

WELDON INSTRUMENTS



Ganjay Wali Street, Rai Pur Stop, Wazirabad Road, Sialkot
51310 Pakistan Tel: +92 52 3571383, E-mail:

wagas@weldoninstruments.com

URL: <https://www.weldoninstrument.com>

21. EXPLANATION OF SYMBOLS USED ON LABEL (EN ISO 15223-1:2020)

SYMBOL	TITLE OF SYMBOL	DESCRIPTION OF SYMBOL	SYMBOL No.
	Manufacturer	Indicates medical device manufacturer, as defined in Regulation (EU) 2017/745	ISO 7000-3082
	Unique device identifier	Indicates a carrier that contains unique device identifier information	.-.
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 7000-2493
	Batch Code	Indicates the manufacturer's batch code so that the batch or LOT can be identified	ISO 7000-2492
	Cautions	Indicates the need for the user to consult the instruction for use for important cautionary information such as warnings and precautions.	ISO 7000-0434A
	Non-Sterile	Indicates a medical device that has not been subject to a sterilization process	ISO 7000-2609
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	ISO 7000-1051
	Keep dry	Indicates a medical device that needs to be protected from moisture	ISO 7000-0626
	Keep away from sunlight	Indicates a medical device that needs protection from light source. This symbol also means keep away from heat.	ISO 7000-0624
	Fragile, Handle with Care	Indicates a medical device that can be broken or damaged if not handled carefully	ISO 7000-0621
	Date of Manufacture	Indicates the date when the medical device was manufactured	ISO 7000-2497
	Use By Date	Indicates the date after which the medical device is not to be used	ISO 7000-2607
	Distributor	Indicating the entity distributing medical device in to the local	ISO 7000-3724
	Importer	Indicating the entity importing medical device in to the local	ISO 7000-3725
	Translation	To identify that the original medical device information has undergone a translation which supplements or replaces the original information.	ISO 7000-3728
	CE Mark	Product Complies with requirements of Directive 93/42/EEC and 4-digit number (0068) reflects identification number of notified body MTIC InterCert S.r.l via G. Leopardi, 14, 20123, Milano (MI), ITALY. Tel. +39 02 97071 800 - Fax +39 02 930 8176 Email: info@mticert.org www.mticert.org	Annex XII of Directive 93/42/EEC
(01) 00000000000000		14 Digit Basic UDI-DI Code (GS1-GTIN)	
(10) 00000000		Lot Number	

SYMBOL	TITLE OF SYMBOL	DESCRIPTION OF SYMBOL	SYMBOL No.																																																								
(11) YYYYMMDD		Date of manufacture																																																									
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<table><tr><th colspan="4">Languages & Code in Europe</th></tr><tr><th>Language</th><th>Code</th><th>Language</th><th>Code</th></tr><tr><td>Bulgarian</td><td>BG</td><td>Irish</td><td>GA</td></tr><tr><td>Croatian</td><td>HR</td><td>Italian</td><td>IT</td></tr><tr><td>Czech</td><td>CS</td><td>Latvian</td><td>LV</td></tr><tr><td>Danish</td><td>DA</td><td>Lithuanian</td><td>LT</td></tr><tr><td>Dutch</td><td>NL</td><td>Maltese</td><td>MT</td></tr><tr><td>English</td><td>EN</td><td>Polish</td><td>PL</td></tr><tr><td>Estonian</td><td>ET</td><td>Portuguese</td><td>PT</td></tr><tr><td>Finnish</td><td>FI</td><td>Romanian</td><td>RO</td></tr><tr><td>French</td><td>FR</td><td>Slovak</td><td>SK</td></tr><tr><td>German</td><td>DE</td><td>Slovenian</td><td>SL</td></tr><tr><td>Greek</td><td>EL</td><td>Spanish</td><td>ES</td></tr><tr><td>Hungarian</td><td>HU</td><td>Swedish</td><td>SV</td></tr></table>				Languages & Code in Europe				Language	Code	Language	Code	Bulgarian	BG	Irish	GA	Croatian	HR	Italian	IT	Czech	CS	Latvian	LV	Danish	DA	Lithuanian	LT	Dutch	NL	Maltese	MT	English	EN	Polish	PL	Estonian	ET	Portuguese	PT	Finnish	FI	Romanian	RO	French	FR	Slovak	SK	German	DE	Slovenian	SL	Greek	EL	Spanish	ES	Hungarian	HU	Swedish	SV
Languages & Code in Europe																																																											
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Hungarian	HU	Swedish	SV																																																								

22. REVISION HISTORY:

Creation & Updating Management			
Status	Rev.#	Section No. & Revision Details	Date
Obsolete	01	New document in compliance with Regulation (EU) 2017/745.	01.01.25
Approved	02	Updated §3.2 Indication for use of 12 variants.	20.10.25
		Updated §3.3 Intended Users of 12 variants.	
		Updated §3.4 Intended Patient Population of 12 variants.	
		Updated §9. Use Instructions / Treatment before Device is Ready for Use.	