

DECLARATION OF CONFORMITY

PRODUCT

General Surgery

MANUFACTURER

SURGICON

SURGICON PVT. LTD.
SURGICON PVT. LTD. P.O. Box No. 244,
Khadim Ali Road Sialkot-51310,
Sialkot, Punjab 51310, Pakistan

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EU DECLARATION OF CONFORMITY MEDICAL DEVICE REGULATION

[MDR EU 2017/745 – Article 19]

“We hereby, under our sole responsibility declare, that the product to which this declaration relates, is in Conformity with the relevant provisions of standards and other normative document(s) and fulfils the essential requirements of EU MDR 2017/745.”

According to **EU MDR 2017/745 CHAPTER V SECTION 1 ARTICLE 51 Classification of devices** are divided into the following classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification has been carried out, in accordance with **ANNEX VIII “CLASSIFICATION RULES”** to the **MDR** and in conjunction with **MDCG 2021-24 Guidance on classification of medical devices**.

The technical documentation to be drawn up by the manufacturer must include the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII of the MDR.

CONFORMITY ASSESSMENT ROUTE

Conformity Assessment Route adopted as per **Article 52 (7) MDR (EU) 2017/745**. Manufacturers of **class Ir** devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the **EU declaration of conformity** referred to in **Article 19** after drawing up the technical documentation set out in **Annexes II and III**.

IDENTIFICATION OF THE LEGAL MANUFACTURER

SURGICON is registered in the EU territory /Union market and according to the provision of Article 10, **MDR (EU) 2017/745 SURGICON**, is declared as a manufacturer.

SURGICON
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DEVICE DESCRIPTION

DEVICE NAME

GENERAL SURGERY TOOLS

DESCRIPTION

PRODUCT NAME	DEVICE DESCRIPTION
1. FORCEPS	Forceps are used when fingers are too large to grasp small objects or when many objects need to be held at one time while the hands are used to perform a task.
2. SCISSORS	Typically used for cutting sutures, dressings, and cutting and dissecting biological tissue.
3. CURETTES	Surgical instruments used to remove or clean any excess of blood or infected tissues using a scraping or scooping motion.
4. CLAMPS	Hold materials together or back during medical procedures, commonly used for blood vessels, tissues, needles, towels, and drapes. Products include hemostats in straight and curved forms, forceps, pliers, and more.
5. KNIFE	A surgical knife with a pointed double-edged blade; used for punctures and small incisions.
6. DENTAL SCALER & RING	Periodontal scalers are dental instruments used in the prophylactic and periodontal care of teeth (most often human teeth), including scaling and root planning.
7. BONE HOLDER	Bone Holding Forceps are specialized instruments used in various veterinary orthopedic surgical operations.
8. PLIERS	The Surgical Pliers are used for cutting, crimping wires, bending, removing pins, manipulating tissue during orthopedic surgeries
9. RETRACTORS	A retractor is a surgical instrument used to separate the edges of a surgical incision/wound or to hold away certain organs and tissues

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10. SCALPEL	A scalpel is a special kind of knife used by doctors, particularly surgeons. Scalpels are small, lightweight, and have a fine, sharp blade.
11. FIXATION FRAME	An external fixator is a stabilizing frame to hold the broken bones in proper position.
12. WEINGART STOMACH OPERATING SET	Weingart's Fixation Frame for Stomach Operating Set for Removing Foreign Bodies from the Rumen
13. GENERAL CHOLECYSTECTOMY SET	A cholecystectomy (koh-luh-sis-TEK-tuh-me) is a surgery to remove the gallbladder.
14. TITANIUM BLUE ROTATING BABY TISCHLER BIOPSY PUNCH	Tischler rotating biopsy punches offer the added convenience of making a quick change in the biopsy tip size and shape without the expense of having additional complete biopsy punches.
15. ROTATING BABY TISCHLER BIOPSY PUNCH GOLD	Cervical biopsy is a surgical procedure in which a small amount of tissue is removed from the cervix. During the colposcopy, the clinician looks at the cervix and biopsies any areas that look abnormal.

INTENDED USE

General surgery tools are used for cutting, grasping, clamping, dissecting, probing, draining, aspirating, suturing, or ligating. Cutting instruments for creating incisions or removing tissue. Grasping instruments for holding or manipulating tissue. Hemostatic instruments for stopping bleeding. All these tools are manufactured by SURGICON and are extensively used by doctors and experts.

INTENDED USER

Doctors especially surgeons use general surgery tools in hospitals. Paramedic staff also uses these tools for first-aid.

LIST OF PRODUCTS & TRADE NAMES

TRADE NAME - SURGICON PVT. LTD.

LIST OF PRODUCT VARIANTS – Attached as ANNEX-1

SPECIFICATIONS

GENERAL SURGERY TOOLS are developed using STAINLESS STEEL GRADE 410 and 420. Multiple tools with different size dimensions are made using state-of-the-art technology.

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DESCRIPTION OF RAW MATERIAL

The material used in these general surgery tools is GRADE 410 AND 420 STAINLESS STEEL. It is corrosion resistant. Surgical tools made from this are reusable.

CLASSIFICATION RULE (ANNEX VIII) EU MDR 2017/745

This declaration relates to **SURGICON PVT. LTD.**, which is classified as **Class Ir (reusable)** by **RULE-6** set out in **Medical Device Regulation (EU) 2017/745, [Annex VIII, and Chapter III]**.

This declaration also classifies the general surgery tools as surgically invasive and reusable according to **RULE 6, Section 1.1, 2.2, and 2.3** respectively, set out in **Medical Device Regulation (EU) 2017/745, [Annex VIII, and Chapter I]**.

CLASSIFICATION AND JUSTIFICATION ANNEX VIII CHAPTER-I of the EU MDR

1. DURATION OF USE

1.1 TRANSIENT - normally intended for continuous use for less than 60 minutes.

2. INVASIVE AND ACTIVE DEVICES

2.3 SURGICALLY INVASIVE DEVICE


(a) Which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and

(b) Which produces penetration other than through a body orifice

2.4 REUSABLE SURGICAL INSTRUMENTS

Instruments intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.

ANNEX VIII CHAPTER III CLASSIFICATION RULES

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5. INVASIVE DEVICES

5.2. RULE 6

All surgically invasive devices intended for transient use are classified as class IIa unless they:

- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;
- **are reusable surgical instruments, in which case they are classified as class Ir;**
- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;
- are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;
- have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or
- are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIIb.

CHAPTER VI

- **ARTICLE 61**

This declaration states that to confirm conformity with Annex I's safety and performance requirements under standard device usage, and assess side-effects and benefit-risk ratio (as in Sections 1 and 8 of Annex I), clinical data providing adequate evidence, including relevant data from Annex III where applicable, must be utilized.

CHAPTER VII SECTION 1

- **ARTICLE 83**

According to this declaration, as per CHAPTER VII, manufacturers must establish, document, and maintain POST-MARKET SURVEILLANCE, VIGILANCE, and MARKET SURVEILLANCE systems that align with the device's risk class and type. This system should be an integral component of the manufacturer's quality management system, as outlined in Article 10(9).

- **ARTICLE 85**

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Class I device manufacturers must create a post-market surveillance report detailing data analysis, conclusions, and any preventive actions. The report, based on the surveillance plan from Article 84, must be updated as needed and provided to authorities upon request.

CHAPTER VII SECTION 2

- **ARTICLE 87**

Manufacturers of devices made available on the Union market, other than investigational devices, shall report, to the relevant competent authorities, in accordance with Articles 92(5) and (7).

- **ARTICLE 89**

After reporting a serious incident as per Article 87(1), the manufacturer must promptly investigate the incident and the devices involved. This investigation includes a risk assessment and appropriate field safety corrective action based on criteria outlined in paragraph 3 of this Article.

HARMONIZED STANDARDS IMPLEMENTED IN COMPLIANCE WITH CONFORMITY IN DECLARATION

STANDARD NUMBER	STANDARD DESCRIPTION
EU MDR 2017/745	Medical Devices Regulation (EU) 2017/745
ISO 13485:2016	Medical devices Quality management systems
ISO 14971:2019	Medical devices Application of risk management to medical devices



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ISO/TR 24971:2020	Medical devices Guidance on the application of ISO 14971
ISO 15223-1:2021	Medical devices Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements
ISO 15223-2:2010	Medical devices Symbols to be used with medical device labels, labelling, and information to be supplied Part 2: Symbol development, selection and validation
ISO 20417:2021	Medical devices Information to be supplied by the manufacturer
ISO 10993-1:2021	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
ISO 10993-2:2022	Biological evaluation of medical devices Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity



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ISO 10993-7:2008	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2021	Biological evaluation of medical devices Part 10: Tests for skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices Part 11: Tests for systemic toxicity
ISO 10993-12:2021	Biological evaluation of medical devices Part 12: Sample preparation and reference materials
ISO 10993-15:2019	Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from metals and alloys
ISO 10993-17:2023	Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents
ISO 10993-18:2020	Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process
ISO/TS 10993-19:2020	Biological evaluation of medical devices



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	Part 19: Physico-chemical, morphological and topographical characterization of materials
ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation
ISO 7151:1988	Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods
ISO 7153-1:2016	Surgical instruments Materials Part 1: Metals
ISO 7740:1985	Instruments for surgery Scalpels with detachable blades Fitting dimensions
ISO 9173-1:2016	Dentistry Extraction forceps Part 1: General requirements
ISO 7741:1986	Instruments for surgery Scissors and shears General requirements and test methods
IEC 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices

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ISO 14155:2020	Clinical investigation of medical devices for human subjects Good clinical practice
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EUROPEAN AUTHORIZED REPRESENTATIVE

- **CMC MEDICAL Devices C/Ancha N2, Mijas Costa, malaga SPAIN**
- **RESRESENTATVE - SURGICON PVT. LTD**

LIST OF PRODUCT VARIANTS (ANNEX I)

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3	J-12-003	Buck Percussion Hammer - Length = 18 cm / 7", With Needle and Brush, Stainless Steel	8
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6	J-12-006	Berliner Percussion Hammer - Length = 17 cm / 6-3/4", Brass	8
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13	J-12-014	Pinard Stethoscope Wooden - Length = 14.5 cm / 5-3/4"	5
14	J-12-015	Townley Caliper - Length = 10 cm / 4"	6
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