



MANUFACTURERS & EXPORTERS OF  
QUALITY SURGICAL, DENTAL, VETERINARY INSTRUMENTS & SCISSORS

SERVING SURGICAL WORLD SINCE 1908

**SURGICON**  
**(PVT) LIMITED**

P. O. Box 244, KHADIM ALI ROAD SIALKOT, 51310, PAKISTAN.  
Tel: +92-52-4262531-32-4262730-31  
Fax: +92-52-4262533-4262733  
E-mail: info@surgicon.com.pk  
Web: www.surgicon.com.pk

## EC DECLARATION OF CONFORMITY

(According to Council Directive 93/42/EEC on Medical Devices)

### 1. Manufacturer

**Surgicon (Pvt.) Ltd.**

Khadim Ali Road

Sialkot-51310

Pakistan

### 2. EU Authorized Representative

**CMC Medical Devices**

C/ Ancha N2

Mijas Costa

Málaga

Spain

### 3. Products Covered by This Declaration

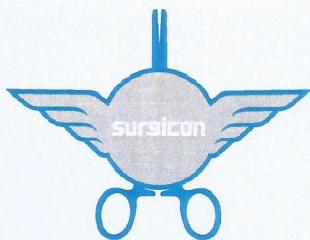
The manufacturer declares conformity for the following **non-sterile reusable medical devices**:

Sr#	Products Name	GMDN Code	CLASS	Role
1	Adenoid curette, reusable	33449	1	6
2	Amputation knife	35131	1	6
3	Basic tracheostomy tube, reusable	38792	1	6
4	Bone Curette, Reusable	31335	1	6
5	Bone Cutting Forceps	46688	1	6
6	Bone File/Rasp, Manual	35559	1	6
7	Bone Holding Forceps	46751	1	6
8	Bone Lever/Elevator	35048	1	6
9	Bone-nailing spacer	47913	1	6
10	Cast Spreader	13708	1	6
11	Common bile duct dilator	11256	1	6



ISO 9001 : 2015  
ISO 13485 : 2016





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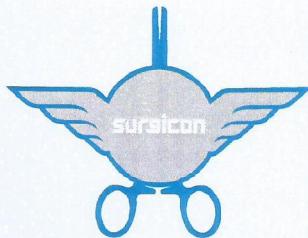
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9	Bone-nailing spacer	47913	1	6
10	Cast Spreader	13708	1	6
11	Common bile duct dilator	11256	1	6
12	Craniofacial rongeur, reusable	33442	1	6
13	Dental dressing forceps, reusable	31814	1	5
14	Dental excavator, reusable	35811	1	6
15	Dental explorer	35812	1	5
16	Dental impression tray, reusable	35850	1	5
17	Dental mirror, reusable	31776	1	5
18	Dental amalgam carrier	35696	1	5
19	Dental amalgam carver, reusable	35793	1	6
20	Dental root elevator	16480	1	6
21	Dental wax carver	35794	1	5
22	Ear speculum, reusable	33395	1	5
23	ENT Diagnostic Set	45085	1	5
24	ENT Trocar Blade	33678	1	6
25	Eustachian catheter, reusable	42451	1	6
26	Eye spud/needle	46549	1	6
27	Eyelid speculum, reusable	35349	1	5
28	Fibreoptic retractor handle	46773	1	6
29	Fistula probe	35252	1	6
30	Fixed-diameter cervical dilator, reusable	11266	1	6
31	Gallstone scoop	13509	1	6
32	General-purpose bowl, reusable	42893	1	1
33	General-purpose calliper, metallic	32262	1	1
34	General-purpose surgical scissors, Reusable	38727	1	6
35	General-purpose surgical spatula	39610	1	6
36	General-purpose syringe, reusable	62182	1	1



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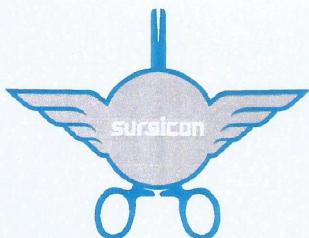
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37	Hand-Held Surgical Retractor, Reusable	45918	1	6
38	Instrument Tray	12143	1	1
39	Intrauterine curette, manual	32594	1	6
40	Lacrimal probe, reusable	13120	1	6
41	Laryngoscope Blade, Reusable	46827	1	6
42	Laryngoscope hanlde, Reusable	46830	1	6
43	Liposuction system cannula, reusable	45414	1	6
44	Manual dental burnisher, reusable	64078	1	6
45	Manual dental scaler, reusable	35320	1	6
46	Manual surgical saw, flexible	44987	1	6
47	Manual surgical saw, rigid	32563	1	6
48	Mouth gag, adjustable, reusable	35085	1	5
49	Nasal septum straightening forceps	62726	1	6
50	Nasal speculum, reusable	35350	1	5
51	Needle Holder, Reusable	12726	1	6
52	Obstetrical forceps, reusable	35082	1	6
53	Open-surgery biopsy forceps, reusable	11775	1	6
54	Open-surgery dissector	11290	1	6
55	Open-surgery ligation clip applier	35798	1	6
56	Ophthalmic soft-tissue surgical forceps, tweezers-like, reusable	62674	1	6
57	Ophthalmic curette, reusable	32772	1	6
58	Orthopaedic joint/limb rongeur	32853	1	6
59	Orthopaedic Osteotome	12844	1	6
60	Paranasal sinus curette	47525	1	6
61	Percussion hammer, manual	11950	1	1
62	Periodontal curette	41660	1	6
63	Periosteal Elevator, Reusable	38168	1	6



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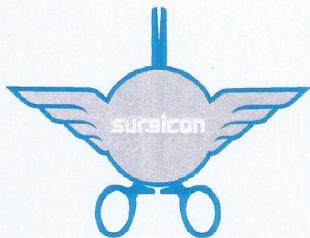
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64	Periotome, reusable	45713	1	6
65	Rectal probe	31965	1	5
66	Rectal dilator, reusable	11262	1	5
67	Rectal speculum	35351	1	5
68	Rib Spreader	13709	1	6
69	Rubber dam clamp	15712	1	6
70	Rubber dam punch	35553	1	6
71	Scalpel Handles, Reusable	12235	1	6
72	Scalpel, Reusable	35141	1	6
73	Skin grafting knife	12253	1	6
74	Soft-Tissue Surgical Hook, Reusable	42595	1	6
75	Sterilization Container	13730	1	1
76	Surgical depth gauge, reusable	32845	1	6
77	Surgical Gouge	35090	1	6
78	Surgical Mallet	32312	1	5
79	Surgical Screwdriver, Reusable	33968	1	6
80	Surgical soft-tissue manipulation forceps, alligator, reusable	62467	1	6
81	Surgical soft-tissue manipulation forceps, scissors-like, reusable	62468	1	6
82	Surgical soft-tissue manipulation forceps, tweezers-like, reusable	62466	1	6
83	Surgical traction tensioner connector	62624	1	6
84	Surgical/emergency suction cannula, non-illuminating, reusable	38749	1	6
85	Suturing needle, reusable	32357	1	6
86	Tongue depressor, surgical	14066	1	5
87	Tonsil dissector, reusable	33452	1	6
88	Tonsil snare	13632	1	6
89	Tooth extraction forceps	35552	1	6
90	Towel Clamp	34961	1	6



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91	Tuning fork	32526	1	5
92	Urethral dilator	11265	1	6
93	Uterine Sound, reusable	13644	1	6
94	Vaginal speculum, reusable	35352	1	5
95	Vascular dilator, reusable	11268	1	6
96	Wire cutter	32885	1	1
97	Wire holding/twisting forceps	32886	1	1
98	Wire holding/twisting pliers	32874	1	1
99	Wire/ligature passer, reusable	32864	1	6
100	Bandage scissors, reusable	13481	1	1

Note: GMDN codes are provided for reference purposes only.

#### 4. Device Classification

In accordance with Annex IX of Council Directive 93/42/EEC, the above-listed devices are classified as:

**Class I – Rule 6 (Surgically invasive devices intended for transient use)**

**Class I – Rule 5 (Non-invasive devices in contact with injured skin)**

**Class I – Rule 1 (Non-invasive devices)**

#### 5. Conformity Assessment Procedure

The conformity assessment has been carried out in accordance with:

**Annex VII – EC Declaration of Conformity  
of Council Directive 93/42/EEC on Medical Devices**

As Class I medical devices, the products do not require Notified Body involvement under the MDD.

#### 6. Declaration of Conformity

We hereby declare, under our sole responsibility, that the medical devices listed above comply with the applicable provisions of Council Directive 93/42/EEC on Medical Devices, as amended.



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The technical documentation demonstrating conformity is maintained at the premises of the manufacturer and shall be made available to the competent authorities upon request.

## 7. Applied Standards

The following harmonized and international standards have been applied, where applicable:

- EN ISO 13485:2016 — Quality management systems
- EN ISO 14971:2019 — Application of risk management to medical devices
- ISO 15223-1:2016 — Symbols for medical device labelling
- ISO 7153-1 — Materials for surgical instruments
- ISO 14644-1:2015 — Cleanrooms and associated controlled environments

## 8. Transitional Provision Statement (Article 120 MDR)

This Declaration of Conformity was originally issued in accordance with Council Directive 93/42/EEC and remains valid under the transitional provisions of Article 120 of Regulation (EU) 2017/745, as amended by Regulation (EU) 2023/607, pending issuance of the MDR certificate by SGS Belgium (Notified Body No. 1639).

## 9. Validity

Valid from: 20 April 2021

Valid until: 20 April 2026

## 10. Authorized Person

Name: Arshad Malik

Position: Responsible Person

On behalf of: Surgicon (Pvt.) Ltd

Place: Sialkot, Pakistan

Signature:



Note: This Declaration of Conformity is issued under the sole responsibility of the manufacturer.



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