

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

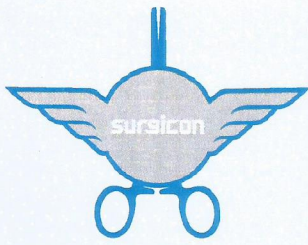
The manufacturer declares conformity for the following non-sterile reusable medical devices:

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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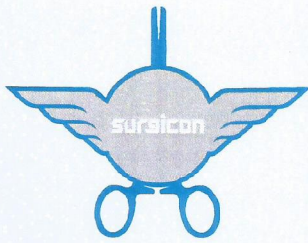
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9	Bone-nailing spacer	47913	1	6
10	Cast Spreader	13708	1	6
11	Common bile duct dilator	11256	1	6
12	Craniofacial rongeur, reusable	33442	1	6
13	Dental dressing forceps, reusable	31814	1	5
14	Dental excavator, reusable	35811	1	6
15	Dental explorer	35812	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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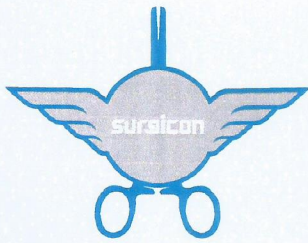
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37	Hand-Held Surgical Retractor, Reusable	45918	1	6
38	Instrument Tray	12143	1	1
39	Intrauterine curette, manual	32594	1	6
40	Lacrimal probe, reusable	13120	1	6
41	Laryngoscope Blade, Reusable	46827	1	6
42	Laryngoscope handle, Reusable	46830	1	6
43	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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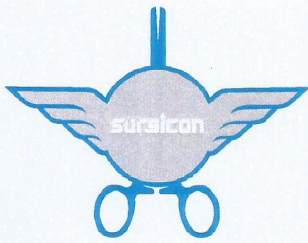
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64	Periotome, reusable	45713	1	6
65	Rectal probe	31965	1	5
66	Rectal dilator, reusable	11262	1	5
67	Rectal speculum	35351	1	5
68	Rib Spreader	13709	1	6
69	Rubber dam clamp	15712	1	6
70	Rubber dam punch	35553	1	6
71	Scalpel Handles, Reusable	12235	1	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.

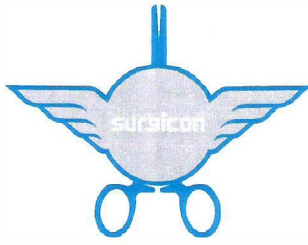
6. Declaration of Conformity

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. Valid from: 20 April 2022
Valid until: 20 April 2027

10. Authorized Person

Name: Arshad Malik
Position: Responsible Person
On behalf of: Surgicon (Pvt.) Ltd

Place: Sialkot, Pakistan

Signature: _____

Arshad Malik
21/01/2026



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



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