



## EC REPRESENTATIVE CERTIFICATE

This is to Certify That, We **Maxcert Germany** acts as EU Authorized Representative for the mentioned manufacturer and agree to perform the duties and responsibilities as the EC REP according to the MDD 93/42/EEC as amended by 2007/47/EC.

CERTIFICATE NUMBER: **MCE/2023/0002046-1**

MANUFACTURER NAME: **SWANTIA MEDICAL (PVT) LIMITED**

COMPANY ADDRESS: P.O.S.I. ESTATE, DEFENCE ROAD, Sialkot - 51310, Pakistan

PRODUCT TYPE & CLASS: Meet the essential requirement of Medical Device Directive 93/42/EEC as amended by 2007/47/EC and falls within manufacturers of Class – I devices (Annex A- Product List)

EUDAMED SRN **PK-MF-000036302**

The manufacturer has ensured to provide us with an appropriate technical documentation and declaration of conformity for the mentioned products (list of products see annex)

The certificate remains valid until the expiration agreement of EC REP, renewed annually, unless manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

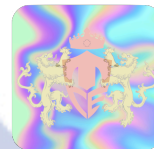
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Issued on: 15/06/2023

Valid until: 14/06/2024



DE/0000050011  
BfArM Germany



Authorized Signatory Certification

**MAXCERT EC REPRESENTATIVE**

This certificate remains the property of Maxcert to whom must be returned when asked and can be withdrawn without notice. Actual EC Rep status can be confirmed from EUDAMED database. This certificate is for the exclusive use of Maxcert's client and is provided as proof of Authorized Representation after the agreement (Mandate) between Maxcert and the client. Maxcert assumes no liability to any loss, expense or damage occurred by the use of this certificate and the Authorized Representative agreement (Mandate). The provided SRN can be verified from EUDAMED database.

**MAXCERT EUREP Heidelbergstr 79, 69190 Walldorf Germany DE-AR-000019569**

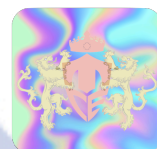
Email: info@maxcert.de Web: www.maxcert.de Ph: +49 6227-6512286



## EC REPRESENTATIVE CERTIFICATE

ANNEX A : Product List ( 1-97)  
Class 1 Medical Devices MDD

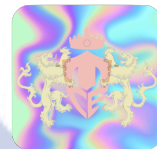
S NO	UMDN Code	PRODUCT NAME
1	10025	Adenotomes
2	16179	Amalgam Carriers
3	16443	Appliers Aneurysm Clip
4	17673	Approximators
5	15275	Awls
6	15554	Basins
7	10339	Bedpans
8	15560	Bougies
9	15561	Bowls
10	10519	Burs
11	10561	Cannulae
12	10685	Catheters
13	10824	Chisels
14	10861	Clamps
15	15573	Cutters
16	16666	Dental Hand Instruments Surgical
17	13938	Dental Syringes
18	11254	Dilators
19	11504	Elevators
20	11701	Files
21	11774	Forceps
22	11950	Hammers Percussion
23	17954	Hand Drills Surgical
24	12028	Hooks
25	12239	Knives
26	12726	Needle Holders
27	12844	Osteotomes
28	13117	Probes
29	13126	Proctoscopes
30	13228	Punches
31	13288	Rasps
32	13373	Retractors
33	13416	Rongeurs





## EC REPRESENTATIVE CERTIFICATE

S NO	UMDN Code	PRODUCT NAME
34	13454	Scalers
35	13480	Scissors
36	13508	Scoops
37	13630	Snares
38	13645	Spatulas
39	15602	Specula
40	13707	Spreaders
41	13823	Strippers
42	13929	Syringes
43	17507	Taps Bone
44	14066	Tongue Depressors
45	15609	Trays
46	14146	Trephines
47	14154	Trocars
48	14257	Tweezers
49	11774	Forceps (Angiotribes, Cranioclasts)
50	10172	Applicators
51	11775	Forceps, Biopsy
52	11084	Curettes
53	16002	Cystotomes
54	11927	Directors, Guides
55	11345	Driver/Extractors
56	11895	Gouges
57	12252	Knives Scalpel
58	12393	Loops
59	12989	Perforators
60	12235	Scalpel Handles
61	16025	Spuds Eye
62	14175	Tubes
63	15621	Vectus
64	10560	Canes
65	11290	Dissectors
66	11587	Enucleators





## EC REPRESENTATIVE CERTIFICATE

S NO	UMDN Code	PRODUCT NAME
67	11720	Finger Protectors
68	11822	Gags
69	12222	Keratomes
70	12421	Mallets
71	12440	Markers
72	12547	Mirrors
73	13287	Raspatories
74	13448	Saws
75	13517	Screwdrivers, Bone
76	13730	Sterilization Containers
77	14099	Tracheotomy Kit
78	14291	Urinals
79	14427	Kick Buckets
80	15572	Cups
81	15580	Extractors
82	15586	Jars
83	15701	Dishes, Petri
84	16875	Pins
85	14255	Tuning Forks
86	13750	Stethoscopes
87	10156	Anoscopes
88	15076	Laryngoscopes Rigid
89	12849	Otoscopes
90	11963	Headlights
91	13594	Sigmoidoscopes
92	12815	Ophthalmoscopes
93	11788	Forceps, Obstetrical
94	15621	Microsurgical Instrument
95	17972	Tubing, Stainless Steel
96	13833	Stylets
97	17640	Cannulae, Liposuction

