

# Certificate of CE-Registration



## mdi Europa

This is to certify that, in accordance with either medical device Directive 93/42/EEC as amended by 2007/47/EC or Directive 98/79/EC, mdi Europa GmbH agree to perform all duties and responsibilities as the Authorized Representative for

Hiermit wird bestätigt, daß mdi Europa GmbH als Bevollmächtigter gemäß § 7 Medizinproduktegesetz (MPG/nationale Umsetzung der Richtlinie für Medizinprodukte 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG) für den Hersteller

**Swantia Medical (Private) Limited**  
**P.O.S.I Estate, Defence Road, Sialkot 51310**  
**Pakistan**

as stipulated and demanded by the afore-mentioned Directives. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

die Anzeigepflicht gemäß § 25 MPG für die nachfolgend aufgeführten Medizinprodukte erfüllt hat. Den angezeigten Medizinprodukten sind die folgenden Registrierdaten zugeordnet worden:

UMDNS Code	Product Group	Class	Reg.No.
10-025	Adenotomes	Class I	DE/CA09/0760/1756
16-179	Amalgam Carriers	Class I	DE/CA09/0760/1762
10-172	Applicators	Class I	DE/CA09/0760/1765
10-174	Applicators, Clip	Class I	DE/CA09/0760/1760
16-443	Appliers Aneurysm Clip	Class I	DE/CA09/0760/1761
17-673	Approximators	Class I	DE/CA09/0760/1772
15-275	Awls	Class I	DE/CA09/0760/1771
15-560	Bougies	Class I	DE/CA09/0760/1769
10-519	Burs	Class I	DE/CA09/0760/1768
10-561	Cannulae	Class I	DE/CA09/0760/1767
16-437	Chairs Examination/Treatment	Class I	DE/CA09/0760/1766
10-824	Chisels	Class I	DE/CA09/0760/1753
10-861	Clamps	Class I	DE/CA09/0760/1750
11-059	Crushers	Class I	DE/CA09/0760/1748
15-572	Cups	Class I	DE/CA09/0760/1746
11-084	Curettes	Class I	DE/CA09/0760/1742
15-573	Cutters	Class I	DE/CA09/0760/1741
13-041	Cutters, Pin and Wire	Class I	DE/CA09/0760/1743
16-666	Dental Hand Instruments Surgical	Class I	DE/CA09/0760/1789

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The manufacturer has provided mdi Europa with all necessary documentation, together with an appropriate Declaration of Conformity confirming that the medical devices fulfill the essential requirements of either Directive 93/42/EEC as amended by 2007/47/EC or 98/79/EC. A safety officer has been appointed for Germany and therefore is in full compliance with § 31 MPG.

Der Hersteller hat mdi Europa alle für das erstmalige Inverkehrbringen von Medizinprodukten erforderlichen Dokumente vorgelegt. Dazu gehört die Konformitätserklärung, die bestätigt, daß die Produkte die grundlegenden Anforderungen der Richtlinie 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG erfüllen. Ein Sicherheitsbeauftragter gemäß § 31 MPG wurde bestellt.

July 2015

Werner Sander  
President & CEO

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UMDNS Code	Product Group	Class	Reg.No.
16-664	Dental Hand Instruments, Orthodontic	Class I	DE/CA09/0760/1787
11-179	Dermatomes	Class I	DE/CA09/0760/1786
11-254	Dilators	Class I	DE/CA09/0760/1785
11290	Dissectors	Class I	DE/CA09/0760/1784
11-345	Driver/Extractors	Class I	DE/CA09/0760/1782
11-504	Elevators	Class I	DE/CA09/0760/1781
16-482	Explorers	Class I	DE/CA09/0760/1780
11-701	Files	Class I	DE/CA09/0760/1778
11-774	Forceps	Class I	DE/CA09/0760/1779
15-710	Forceps, Dental	Class I	DE/CA09/0760/1777
15-915	Furniture Patient Room	Class I	DE/CA09/0760/1776
11-822	Gags	Class I	DE/CA09/0760/1775
11-895	Gouges	Class I	DE/CA09/0760/1774
11-950	Hammers Percussion	Class I	DE/CA09/0760/1825
17-954	Hand Drills Surgical	Class I	DE/CA09/0760/1745
11-963	Headlights	Class I	DE/CA09/0760/1751
12-028	Hooks	Class I	DE/CA09/0760/1757
14-427	Kick Buckets	Class I	DE/CA09/0760/1763
12-239	Knives	Class I	DE/CA09/0760/1764
12-252	Knives, Scalpel	Class I	DE/CA09/0760/1823
24-022	Laryngoscope Handles	Class I	DE/CA09/0760/1790
15-076	Laryngoscopes Rigid	Class I	DE/CA09/0760/1820
15-075	Laryngoscopes, Flexible	Class I	DE/CA09/0760/1808
12-393	Loops	Class I	DE/CA09/0760/1821
12-421	Mallets	Class I	DE/CA09/0760/1819
12-423	Mallets, Bone	Class I	DE/CA09/0760/1817
12-440	Markers	Class I	DE/CA09/0760/1758
12-549	Mirrors Laryngeal	Class I	DE/CA09/0760/1773
12-726	Needle Holders	Class I	DE/CA09/0760/1770
12-766	Nippers, Malleus	Class I	DE/CA09/0760/1755
12-815	Ophthalmoscopes	Class I	DE/CA09/0760/1754
12-844	Osteotomes	Class I	DE/CA09/0760/1752
12-849	Otoscopes	Class I	DE/CA09/0760/1749
13-117	Probes	Class I	DE/CA09/0760/1747
13-126	Proctoscopes	Class I	DE/CA09/0760/1744
13-228	Punches	Class I	DE/CA09/0760/1788
13-287	Raspatories	Class I	DE/CA09/0760/1759
13-288	Rasps	Class I	DE/CA09/0760/1824
13-373	Retractors	Class I	DE/CA09/0760/1783
13-416	Rongeurs	Class I	DE/CA09/0760/1822

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UMDNS Code	Product Group	Class	Reg.No.
13-448	Saws	Class I	DE/CA09/0760/1807
17-858	Saws, Bone, Rhinoplasty	Class I	DE/CA09/0760/1818
13-454	Scalers	Class I	DE/CA09/0760/1816
12-235	Scalpel Handles	Class I	DE/CA09/0760/1815
13-480	Scissors	Class I	DE/CA09/0760/1814
13-508	Scoops	Class I	DE/CA09/0760/1813
13-517	Screwdrivers, Bone	Class I	DE/CA09/0760/1812
13-630	Snares	Class I	DE/CA09/0760/1811
13-645	Spatulas	Class I	DE/CA09/0760/1810
15-602	Specula	Class I	DE/CA09/0760/1809
13-664	Specula Nasal	Class I	DE/CA09/0760/1804
13-665	Specula Rectal	Class I	DE/CA09/0760/1805
13-666	Specula Vaginal	Class I	DE/CA09/0760/1806
13-707	Spreaders	Class I	DE/CA09/0760/1803
13-730	Sterilization Containers	Class I	DE/CA09/0760/1802
16-017	Stools	Class I	DE/CA09/0760/1801
13-823	Strippers	Class I	DE/CA09/0760/1800
16-585	Syringes, Cartridge	Class I	DE/CA09/0760/1799
14-066	Tongue Depressors	Class I	DE/CA09/0760/1798
15-609	Trays	Class I	DE/CA09/0760/1797
14-154	Trocars	Class I	DE/CA09/0760/1796
16-883	Suction Tips, General-Purpose	Class I	DE/CA09/0760/1795
16-779	Tubing, Suction	Class I	DE/CA09/0760/1794
14-255	Tuning Forks	Class I	DE/CA09/0760/1793
14-257	Tweezers	Class I	DE/CA09/0760/1792
14-291	Urinals	Class I	DE/CA09/0760/1791

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