

CERTIFICATE



Registration No. DCS/9479903

Application of Council Directive 93/42/EEC as updated directive 2007/47/EC for Class I
Medical Devices

This is certifying that the products submitted are:

**CLASS I MEDICAL DEVICES
(Re-Useable, Non-Powered Surgical Instruments)**

Manufactured By:

SURGICON PVT LTD

P.O. Box: No. 244, Khadim Ali Road, Sialkot-Pakistan

Comply with the applicable requirements of the Directive 93/42/EEC as updated directive
2007/47/EC for Class I Medical Devices

The Technical file of the products have been assessed according to the procedure of
Conformity Assessment described in the Annex -I, Annex VII.

Limitations:

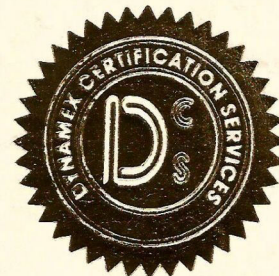
The manufacturer must inform DCS of any substantial changes occurred in the Product or
process in order to examine whether this certificate remains valid. Conformance to all the
regulatory requirements is the sole responsibility of the manufacturer including the appointment
of EU Authorized Representative and registration with concerned competent authority

CHAIRMAN

SCHEME MANAGER

Issue Date: 09 April, 2020

Expiry Date: 08 April, 2021





MANUFACTURERS & EXPORTERS OF
QUALITY SURGICAL DENTAL VETERINARY INSTRUMENTS & SCISSORS

Surgicon
LTD

P. O. Box # 244, Khadim Ali Road,
Sialkot - Pakistan.
Fax: +92-52-262533 & 262733
Phone: +92-52-262531-32 & 262730-32
E-MAIL: jilani@surgicon.com.pk

DECLARATION OF CONFORMITY

SURGICON LTD

Head Office: P.O. Box: No: 244, Khadim Ali Road, Sialkot - PAKISTAN.

We hereby declare under our sole responsibility that the product

- Surgical Instruments (Re-Usable, Single Use)
- Dental Instruments (Re-Usable, Single Use)

the list of instruments is attached to this declaration (annex - 6 file)

Fall within Class – I medical devices and meet the essential requirements of Directive 93/42EEC as update directive 2007/47/EEC and we are also registered with Dinamex Certification Service (DCS) and quality audits of ISO 9001:2015 and ISO 13485:2012+AC:2012 To which this declaration related is in conformity with the following standard(s) or other normative document(s)

ISO 9001:2015

ISO 13485:2016

93/42EEC as update directive 2007/47/EC

Authorised Signatory:


FAZAL JILANI /CEO



19-08-2020
Date



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Anex 1 Medical Products TO THE DECLARATION OF CONFORMITY

SURGICON LTD

Head Office: P.O.Box: No: 244, Khadim Ali Road, Sialkot - PAKISTAN.

I. INSTRUMENTE MEDICALE SONDATE, BUJII, CU ACCESORII:

Инструменты медицинские зондирующие, бужирующие, с принадлежностями:

1. RO: Sonde medicale, mini, micro, standard, drepte, curbe

RU: Зонды: медицинские, мини, микро, стандартные, прямые, изогнутые

EN: (Expolorers Medical),

- **dentare** /зубные / Dental Expolorers, Universal,
- **uterine** /маточные /Uterine Sounds, Sims, Martin, Galabin,
- **chirurgicale** /хирургические / Surgical Probes, Directors, Maya, Varady, Nabatoff, Bowman, Ear, Guthrie, Nosal, Veachik, Atic, Buttoned Probes, Doyan, Cotton Probes, Grooved, Twisted.

2. RO: Instrumente pentru plombare

RU: Инструменты для пломбирования

EN: Filling instruments

- **fuloar -netezitor** /шпонфер-гладилка /Smother-Plugger, Hollenback, Ward, Black, Lordmore, Mortonson.

3. RO: Canule medicale

RU: Канюли

EN: Cannula, Medical

- **pentru irigareea atticului** / для промывания аттика / Hartmann,
- **pentru irigareea sinusurilor** / для промывания гайморовой пазухи / Snares, Killian, Kulikov.

4. RO: Tuburi medicale

RU: Трубки

EN: Medical tubes

- **tuburi pentru aspiratie** / трубки аспирационные / suction tubes, Poole, Yankaur, Frazier, Fergusson, Nilson, Nubore,
- **tuburi traheostomice** / трубки трахеостомические / - Jakson, Fullcer, Cubley.

5. RO: Catetere

RU: Катетеры

EN: Medical Catheters,

- **uretrale** / уретральные / Urethral Catheters, Mercier, Coxeter, Lucae.





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6. **RO: Bujii uretrale**
RU: Бужси уретральные
EN: Urethral Bougies
7. **RO: Instrumente pentru drenajul cavității pleurale**
RU: Инструменты для дренирования плевральной полости
EN: Drain, Coakley.
8. **RO: Olive (baloane) pentru insuflarea aerului în nas și ureche**
RU: Оливы (баллоны) для продувания носа и уха
EN: A. Politzer.
9. **RO: Instrumente pentru introducerea amalgamului în cavitatea dentară**
RU: Инструменты для введения амальгамы в полость зуба
EN: Amalgam Carriers

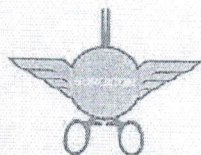
Accesorii/Принадлежности/ Accessory

1. **Cutie pentru depozitare și sterilizare a instrumentelor /** Коробка для хранения и стерилизации инструментов / Sterilizing Drum.
2. **Tăvă pentru instrumente /** Лоток для инструментов / Instruments Trays
 - **dreptunghiulară /** прямоугольный / Instruments Trays /,
 - **rotundă /** лоток круглый / Round Trays,
 - **reniformă /** лоток почкообразный / Kidney Trays,
 - **tavă perforată dreptunghiulară /** лоток прямоугольный перфорированный / Instrument Box Perforated,
 - **capac pentru tavă /** крышка для лотка / Lid for Trays.
3. **Pahar pentru instrumente /** Стакан для инструментов/ Forceps Jars.

II. INSTRUMENTE MEDICALE DE TĂIERE ȘI DE ȘOC CU MARGINI ASCUȚITE (TĂIETOARE), CU ACCESORII:

Инструменты медицинские режущие и ударные с острой (режущей) кромкой, с принадлежностями:

1. **RO: Foarfece medicale:** mini, micro, standard, articulate, din aliaj dur, vasculare, drepte, în unghi, curbate,
RU: Ножницы: медицинские, мини, микро, стандартные, артикуляционные, твердосплавные, сосудистые, прямые, угловые, изогнутые
EN: Scissors, Medical, Metzenbaum, Deavers, Operating, Incision, Mayo, Joseph, De Bakey, Mayo Stille, Lexer, Surgical, Diethrich, Sitlinkin, Schoemaker, Caspar, Metzenbaum-Nelson, Kilner, McIndoe, Strully, Yankauer, Dean, Heyman, Beckman, Spencer, Heath, Universal, Braun-Stadler, Busch, USA Patt, Dissecting, Doyen, Sims, Kelly, Iris, Strabismus, Westcott, Stevens, Enterotomy, Beebee, Lister, Knowles, Esmarch, Smith, Scutin, Bruns, Collen, Cuticle, Stille, Hartman, Noyes, Wecker, Castroviejo, Quinby, Neumann, Fino, Albe, Ross, Metly.
2. **Bisturie:** mini, micro, standard, drepte, în unghi, curbate
RU: Скальпели: мини, микро, стандартные, прямые, угловые, изогнутые
EN: Scalpels, Medical, Surgical, standard, Collin, Dieffenbach, Adams, Parker, Graefe, Buck, Cataract, Beer, Jaeger, Knapp, Bowmann) **cu miner din plastic / с пластмассовой ручкой /** Surgical scalpel with plastic handle, **lame chirurgicale /** лезвия хирургические /Surgical blades



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3. **RO: Cuțite:** mini, micro, standard, drepte, în unghi, curbate
RU: Ножи: мини, микро, стандартные, прямые, угловые, изогнутые
EN: Knife, Medical, Liston Amputation, Langenbeck Amputation, Caltin, Brain, Esmarch, Razor, Amputation, Ballenger, Gritman, Brophy, Knapp, Ziegler, Foreign-body, Bruenings, Lynch, Freer, Lessman
4. **RO: Ferăstraie**
RU: Пилы
EN: Saws, Medical, Engel, Jeglia, Charriege, Satterlee, Post Morten, Joseph, Bergmann, Olivercrona, Miller, Selding
5. **RO: Dălți**
RU: Долота
EN: Chisels, Medical, Osteotomes, Stille, Freer, Killian, Ballenger, Lucas, Gardner, Partsch, Gougeg, Zielke, Lexer
6. **RO: Elevatoare, decolatoare (raspatory): chirurgicale, dentare, drepte, în unghi, curbate**
RU: Элеваторы, распаторы: хирургические, зубные, прямые, угловые, изогнутые
EN: Elevators Dental, Surgical, Bein, White, Luxator, Kopp, Freer, Coleman, Heidbring, Apical, Flohr, Silding, Molt, Cryer, Miller, Winter, Mead, Barry, Williger, Farabeuf, Doyen, Semb
7. **RO: Clești : mini, standard, din aliaj dur, drepte, în unghi, curbate**
RU: Кусачки: мини, стандартные, твердосплавные, прямые, угловые, изогнутые,
EN: Cutters Medical Liston, Sauerbruch, Liston-Key, Ruskin-Liston, Stille-Liston, Kerrison, Ferris-Smith, Jurasz, Beyer, Fulton, Cushing, Casper, Collin, Doyen, Superling-Love, Conchotome, Hartman, Colclouge, Oldberg, Well, Hajek, Takahashi, Stroycken, Ferris-Smith, Hajek-Kosler, Lure, Lempert, Stille-Luer, Ruskin, Leksell-Stille, Blumen, Mead, Jegoroff-Freidin, Dahlgren, Lansen, Haglund, Wire Cutter, Giertz-Stille, Brunner, Wittner, Alexander, Janson, Smith-Peterson.
8. **RO: Chiurete: mini, standard, drepte, înclinate, curbate**
RU: Кюретки: мини, стандартные, прямые, угловые, изогнутые
EN: Curettes, Medical, Sims, Recamaier, Thomas, Volkmann, Beckmann, Caspar, Tessier, Simon, Hemingway, Martin, Willigner, Gracey, Molt, Freer, Gross, Barker, Greene.
9. **RO: Anse : polipe**
RU: Петли: полипные
EN: Snares, Eves, Bruening, Krauze, Krauze-Voss.
10. **RO: Instrumente pentru îndepărtarea pietrei dentare**
RU: Инструменты для удаления зубного камня
EN: Scalers, Darby-Perry, Black, About, Scharmann, Younger-Good.
11. **RO: Exavatoare: chirurgicale, dentare**
RU: Экскаваторы: хирургические, зубные
EN: Excavators, Scalers, Octo, Dardy-Perry, White, Gillet, Caspar, Tompkins, Rhein, Muehlemann.

Accessorii/ Принадлежности/ Accessory

1. **Miner pentru scalpel, pentru Ferăstrău/ Ручка для скальпеля, для пилы/ Scalpel Handles, Saw Handles.**
2. **Cutie pentru depozitarea și sterilizarea instrumentelor/ Коробка для хранения и стерилизации инструментов / Sterilizing Drum /**
3. **Tava pentru instrumente: dreptunghiular /Лоток для инструментов: прямоугольный / Instruments Trays, Tava rotunda / Лоток круглый /Round Trays, Tava reniformă / лоток почкообразный /Kidney Trays/ Tavă perforată dreptunghiulară/ лоток прямоугольный перфорированный/ Instrument Box Perforated Capac pentru tava / крышка для лотка /Lid for Trays**
4. **Pahar pentru instrumente/ Стакан для инструментов/ Forceps Jars.**



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III. INSTRUMENTE MEDICALE DE PĂRTĂTOARE, CU ACCESORII

Инструменты медицинские отщесняющие, с принадлежностями:

1. **RO: Depărtător : medical, mini, standard**
RU: Расширители: медицинские, мини, стандартные
EN: Retractors, Medical, Dilators, Gosset, Daver, Hook, Farabeuf, Kocher, Maty, Volkmann, Cusco, Sims, Otto, Doyen, Hegar, Finochieto, Hank, Nelson, Molt, Bozem, Tuffier, Taylor, Deaver, Caspar, Cushing, Finochietto, Morris, Yasargil, Laila, Codman, Collin, Weitlaner, Jegoroff-Freidin, McIntosh, Haight, Kirschner Beckmann, Miller, Roser-Koeling, Heister, Desmarres, Ramfin, Antin, Jansen, Lardenois, Mellinger, Mueller, Davis-Bayle, Langenbeck, Balfour, Adson, Roux, Tudor Edwards, Nissen, Wylie, Goodell, Sims, Braun.
2. **RO: Oglinzi: mini, standard**
RU: Зеркала: мини, стандартные
EN: Specula, Medical, Cusco, Sims, Doyen, Otto, Auvard, Kristeller, Mathieu, Daines, Sadrif, Kelly, Gabriel, Bodenhammer, Vienna, Killian, Thudichum, Sims, Mathieu, Kelly, Gabriel, Mouth Mirror, Voltolin, Dental Mirror, pâlnie Hartman, Siegle.
3. **RO: Spatule medicale**
RU: Шпатели медицинские
EN: Spatulas, Medical, Maya, Buchwald, Wheeler, Toung, Hartman, Tantal, Boswort, Well, Cement, Era.
4. **RO: Fuloar-netezitor dentare**
RU: Штопферы-гладилки зубные
EN: Hollenback, Lardmount, Mortonson, Black, White, Ward.
5. **RO: Cârlițe**
RU: Крючки
EN: Hooks Medical, Graefe, Ear, Guthrie, Nosal, Graham, Caspar, Cushing, Yasargil, Farabeuf, Varady, Oesch, Muller, Cooly, Kocher, Sachs, Smellie, Braun, Targett, Tracheal Hooks, Kilner, Gillies.
6. **RO: Linguri de amprentă**
RU: Оттисковые ложки
EN: Impression Tray, Perforated, Solid, Lower, Upper.
7. **RO: Excavatoare**
RU: Экскаваторы
EN: Excavators
8. **RO: Linguri medicale**
RU: Ложки медицинские
EN: Spoon, Medical, Volkmann, Weber, Hemingway, Caspar, Williger, Snellen.
9. **RO: Extractoare**
RU: Экстракторы
EN: Extractors, Medical, Varady, Oesch, Muller, Vme, Caspar, Cushing, Yasargil, Farabeuf, Kocher.
10. **RO: Otoscop**
RU: Отоскопы для осмотра уха
EN: Otoscope



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11. RO: Disectoare

RU: Диссекторы

EN: Dissector, Varady, Oesch, Medical, Muller, McDonald, Cheyne, Axenfeld, Wheeler.

12. RO: Laringoscoape

RU: Ларингоскопы для осмотра горла

EN: Laryngoscope

Accesorii/Принадлежности/ Accessory

1. **Miner pentru oglindă / Ручка для зеркал / Mirror Handles.**
2. **Cutie pentru depozitarea și sterilizarea instrumentelor / Коробка для хранения и стерилизации инструментов / Sterilizing Drum /**
3. **Tava pentru instrumente: dreptunghiular / Лоток для инструментов: прямоугольный / Instruments Trays, Tava rotunda / Лоток круглый / Round Trays, Tava reniformă / лоток почкообразный / Kidney Trays/ Tavă perforată dreptunghiulară / лоток прямоугольный перфорированный / Instrument Box Perforated Capac pentru tava / крышка для лотка / Lid for Trays**
4. **Pahar pentru instrumente / Стакан для инструментов / Forceps Jars.**

IV. INSTRUMENTE MEDICALE CU ACȚIUNE DE FIXARE, CU ACCESORII

Инструменты медицинские многоповерхностного воздействия (зажимные), с принадлежностями:

1. RO: Pense medicale mini, micro, standard, articulate, vasculare, drepte, în unghi, curbate

RU: Зажимы: медицинские, мини, микро, стандартные, артикуляционные, сосудистые, прямые, угловые, изогнутые,

EN: Forceps, Medical, Haemostatic, Rochester Pean, Mosquito, Pean, Roch Ochsner, Kocher, Halsted Mosquito, Mikulicz, Collin, Maier, Gross, Cheron, Backhaus, Jones, Schroeder, Millin, Katlin, Polyps, Museux, Satinky, Lister, Bryant, Moya, Magill, Doyen, DeBakey, Ballenger, Kelly, Clamps, Bulldog, Crile, Kelly-Rankin, Spencerwells, Lovelace, Pennington, Crile-Rankin, Rummel, Willet-Martel, Kilner, Maya Ronson, Dieffenbach, Mixer, Heiss, Lower, Allis, Doyan, Nussbaum, Adbie, Scudder, Kocher, Payr, Rubber-Dam, Sarot, Faine, Raney, Teale, Hartmann, Finochietto, Cheatle, Harrison, Saenger.

2. RO: Pensete medicale mini, micro, standard, articulate, din aliaj dur, vasculare, drepte, în unghi, curbate

RU: Пинцеты: медицинские, мини, микро, стандартные, артикуляционные, твердосплавные, сосудистые, прямые, угловые, изогнутые

EN: Tweezers, Thumb, Tissue, Medical, Adson, Michel, Child, DeBakey, College, Merain, Epilation, Lenidin, Verbrugge, Graefe, Hess, Fischer, Arruga, Elsching, Fuchs, Dastoor, Ayer, Lampbert, Desmarres, Knapp, Bipolar, Troeltsch, Lucae, Jansen, Potts-Smith, Taylor, Brophy, Cushing, McIndoe, Semkin, Russain, Bonney, Splinter.

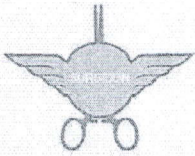
3. RO: Port instrumente, port ac mini, micro, standard, articulate, din aliaj dur, vasculare, drepte, în unghi, curbate

RU: Держатели, Иглодержатели мини, микро, стандартные, артикуляционные, твердосплавные, сосудистые, прямые, изогнутые

EN: Needle Holders, Medical, Mayo- Hegar, Wright, Finochietto, Mayo, Metzenbaum, Castroviejo, Derf, Collier, DeBakey, Crile-Murray, Sarot, Crile-Wood, Olson, Crile, Jacobson, Cartridge, Macphail, Collier, Webster, Mathieu

- **pensa de prins limba / языкодержатели / Guy, Collin, Young**

- **pensa de sustinere a osului / костодержатели / Bone forceps, Holder.**



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4. **RO: Cleste medicale, mini, micro, standard, vasculare, drepte, curbate**

RU: Щипцы: медицинские, мини, стандартные, сосудистые, прямые, изогнутые,

EN: Forceps, Medical, Ferguson, Schroeder, Duplay, Sponge, Polyps, Gray, Finocchio, Ballenger, Foerster, Bozeman-Douglas, Moya, Allis, Museux, Hakansson, Janson, , Metly, Caspar, Cushing, Citelli, De-Lee, Naegele, Piper, Wolff, Horsley, Foerster

Pense biopsie / щипцы биопсийные / Biopsy Forceps, Yeoman, Thomas, Wittner, Alexander, Faure, Van-Doren, Circumcision Clamp

Forceps / корнцанги / Maier, Gross

Pense uterine / щипцы маточные / Uterine Forceps

Pense dentare pentru tehnicieni / щипцы зуботехнические / Dental Pliers

Pense dentare / щипцы зубные / Dental Forceps, English, Klien, Upper, Lower, American, Ralk, Albrecht, Arthur

5. **RO: Ciocane medicale**

RU: Молотки медицинские

6. **EN: Hammers, Medical, Williger, Buck, Doyan, Taylor, Collin.**

Accesorii/ Принадлежности/ Accessory

1. **Pelvimetru / Тазомер / Pelvice Metter Martin.**

2. **Cutie pentru depozitarea și sterilizarea instrumentelor/ Коробка для хранения и стерилизации инструментов / Sterilizing Drum /**

3. **Tava pentru instrumente: dreptunghiular / Лоток для инструментов: прямоугольный / Instruments Trays, Tava rotunda / Лоток круглый / Round Trays, Tava reniformă / лоток почкообразный / Kidney Trays/ Tava perforată dreptunghiulară/ лоток прямоугольный перфорированный/ Instrument Box Perforated**

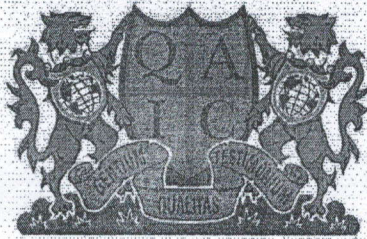
Capac pentru tava / крышка для лотка / Lid for Trays

4. **Pahar pentru instrumente/ Стакан для инструментов/ Forceps Jars.**



19-08-2020

Certificate of Registration



The Governing Board of
Q.A. International Certification Limited
hereby grants to:

SURGICON (PVT) LTD

Registration No.: QAIC / PK / 889 - B

(hereinafter called the Registered Company) the right to be listed in the Directory of Registered Companies in respect of the services listed below. These services shall be offered by the Registered Company at or from only the address given below in accordance with the quality management system in Compliance with the Requirements of ISO 13485:2016.

Address to which this Certificate refers:

P.O. Box: No: 244, Khadim Ali Road, Sialkot - Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Non-Active Surgical and Dental Instruments.

(Please note that the above scope represents the certified activity of the named organisation and as such, the organisation may undertake additional activities that are not covered under this certification).

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

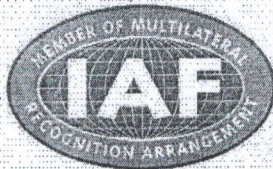
Certificate Issue Date: 1st April 2019 - Certificate Renewal Before: 31st March 2020
Date of Initial Registration: 28th April 2006 - Re-Certification Before: 31st March 2021

This Certificate of Registration is granted subject to the Regulations approved by the Board.

QA INTERNATIONAL

Q.A. International Certification Ltd.
Dudley Court
Dudley Road
Darlington
United Kingdom
DL1 4GG

Tel: +44 (0)1325 384272
Fax: +44 (0)1325 480980
www.qai.co.uk



The use of the Accreditation Mark indicates
accreditation in respect of those activities covered
by the accreditation certificate number 046