



CERTIFICATE OF COMPLIANCE

Certificate # DCS/9479903

This is to certify that

SURGICON PVT LTD

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

Has been assessed against the applicable requirements of directive 93/42/EEC as updated directive 2007/47/EC for CE Marking Class I Medical Devices and found to meet the requirements of directives satisfactorily and is registered with Spanish Competent Authority through EU AR CMC Medical Devices & Drugs, S.L.

PRODUCTS:

Stainless steel Surgical and Dental Instruments (Reusable and Non-Powered)

EU AUTHORISED EU REPRESENTATIVE:

CMC MEDICAL DEVICES & DRUGS, S.L

C/ Horacio Lengo n18

C. P 29006

Málaga-Spain

This assessment exercise was carried with all due care, though regular conformance to all the regulatory requirement is the sole responsibility of manufacturer.

Business Manager:

Issue Date: 08-08-2022

Expiry Date: 07-08-2023

To verify the validity of Certificate, please www.dynamexcertification.org

R01





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: (Explorers Medical),

- **dentare** /зубные / Dental Explorers, 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** /штопфер-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, Fuller, 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: Бужу 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

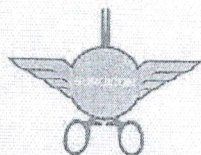
Accessorii/Принадлежности/ Accessory

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, Ferries-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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MANUFACTURERS & EXPORTERS OF
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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, Finochietto, Hank, Nelson, Molt, Bozem, Tuffier, Taylor, Deaver, Caspar, Cushing, Finochietto, Morris, Yasargil, Laila, Codman, Collin, Weitlaner, Jegoroff-Freidin, McIntosh, Haight, Kirschner Beckmann, Miller, Roser-Koeing, Heister, Desmarres, Ramtin, 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, pâlne 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, Cooley, 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, Lambert, 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, Finochietto, 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.

Accessorii/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 2021 - Certificate Renewal Before: 31st March 2022
Date of Initial Registration: 28th April 2006 - Re-Certification Before: 31st March 2024

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.

Certificate of Registration



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

SURGICON (PVT) LTD

Registration No.: QAIC / PK / 889 – A

*(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 **ISO 9001:2015**.*

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 Surgical, Dental, Manicure and Pedicure 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: 28th April 2021 - Certificate Renewal Before: 27th April 2022
Date of Initial Registration: 28th April 2006 - Re-Certification Before: 27th April 2024

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

QA INTERNATIONAL

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



Government of Pakistan

Pakistan Council of Scientific & Industrial Research

PCSIR- CAST METALS & FOUNDRY TECHNOLOGY CENTRE

Punjab Small Industries Estate, Daska



CMFT/20/28451

Dated:27-07-2020

TEST REPORT

In respect of M/s Surgicon Sialkot Pakistan
Centre / Division / Section Industrial Research & Development Section
Sample Name Operating Scissor
Your reference Letter No. / Date Nil/08-07-2020
Client's Sample Nos. 01

Task

The CFC Center Sialkot was asked to provide the Chemical Analysis as per provided Sample .

1. Chemical Analysis Results

Element	Percentage	Element	Percentage
Carbon (C)	0.288	Silicon (Si)	0.344
Phosphorus (P)	0.027	Sulphur (S)	0.022
Manganese (Mn)	0.496	Nickel (Ni)	0.274
Chromium	12.675	Iron (Fe)	Balance

The above mentioned chemical Composition appears to be of AISI 420 J2

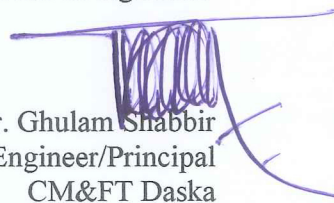
This analytical / test report is based solely on the particular samples (s) supplied by the party and should not be reproduced in part. Sampling has not been performed by the PCSIR-CM&FT and it does not accept the responsibility that the samples (s) supplied is/are truly representative samples (s) of any batch or stock or entire production. While the CM&FT agrees to take every reasonable precaution to ensure validity of its test results, it assumes no liability for the accuracy thereof beyond the amount of the fee charged for the analysis/test. The party shall assume full responsibility for the ethical use of the results in the analysis/test reports and the laboratory shall be held free from any and all claims which may result from the use of such data by the party or other. After completion of the report the sample will be preserved for one month until negotiated otherwise

Industrial Research & Development Section.


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HARDNESS TEST REPORT

Item Code: J-22-1230

Item Description: Wertheim Scissors 18cm

Material: AISI 420 J2

Hardness Value: ☐ 42 – 46

☒ 48 – 52

SR. #	ACTUAL HARDNESS	HARDNESS AFTER ANNEALING
1	50	
2		
3		
4		
5		
Range (Samples): 48-52 HRC		Mean Value: HRC

Approved By:

Name:

Muhammad Ijaz



Signature:

Date: 25-08-2022