

Book No.B 13157

QDP/7.5/MSD/F-04

Serial No.B 1315607

MEMBERSHIP CERTIFICATE

MEMBERSHIP NO: 81171 - A

Name & address of Chamber **The Lahore Chamber of Commerce & Industry**

Association
XXXXXXXXXX

11 Shara-e-Aiwan-e-Sanat-o-Tijarat, Lahore.

(Affiliated with the Federation of Pakistan Chambers of Commerce & Industry)

CERTIFIED that **M/s TRIPLE HELIX SOLUTIONS**

(name and address of Member Firm / Company)

19-D-II WAPDA TOWN, LAHORE

G.S.T. No. N.T.N. No. **2688203-5**

is a member of this Chamber **Since 11/01/2014**

Association
XXXXXXXXXX

THIS CERTIFICATE shall be valid upto the **31 MAR 2024** unless
(date)

otherwise notified to the NTN / GST Registration authority / Scheduled Bank
concerned.



Given on this **20** day of **Jan** 20**23**

Signature of Secretary General

[Signature]

Countersigned by

[Signature]

Muhammad Adnan Khalid Butt
(name and designation)
Vice President 2022-2023

CERTIFICATE

Certificate # QMS/1449

This is to certify that the facility of

TRIPLE HELIX SOLUTIONS

PL NO.19-D-II, WAPDA TOWN, LAHORE-PAKISTAN

The Facility of the below mentioned organization has been evaluated and audited against Good Manufacturing Practices (GMP), Requirement 21 CFR, PART 820 (Import Alert 76-01). The factory quality management system conforms to the requirements of GMP, FDA, See webpage link www.accessdata.fda.gov/cfsia/importalert_224.html.

Products: Surgical and Dental Instruments.

This assessment exercise was carried with all due care on the request of manufacturer, though regular conformance to all the regulatory requirements is the sole responsibility of manufacturer. QMSci is not affiliated with FDA USA.



Business Manager:

Issue Date: 06-03-2020

Expiry Date: 05-03-2021

To verify the validity of Certificate, please visit www.qmsci.org

R01



USA - UK - UAE - PAKISTAN - AUSTRIA - EGYPT - CHINA

This document is issued by QMSci subject to its Certification Terms and Conditions accessible from www.qmsci.org. Consideration is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. Unauthorized modification, imitation or misrepresentation of the content or appearance of this document is unlawful and delinquents may be prosecuted to fullest extent of law.

CERTIFICATE GMP

Registration No: QMS/1449

This is to certify that
TRIPLE HELIX SOLUTIONS
PL NO.19-D-II, WAPDA TOWN, LAHORE-PAKISTAN

Is indigenous manufacture of

SURGICAL AND DENTAL INSTRUMENTS

The facility of the below mentioned organization has been evaluated and audited against Good Manufacturing Practices (GMP), Requirement 21 CFR, PART 820 (Import Alert 76-01). The factory quality management system conforms to the requirements of GMP, FDA USA. See webpage link www.accessdata.fda.gov/cms_ia/importalert_224.html.

While all due care and skill was exercise in carrying out this assessment, however regular conformance to all the regulatory requirements is the sole responsibility of the manufacturer.

This is not a legal document and cannot be used as such.


SCHEME MANAGER

Issue date: 06-03-2019

Expiry date: 05-03-2020

Number of sites: single site (01)

Remains valid subject to satisfactory surveillance audit.

To verify the validity of this certificate, please visit: www.qmsci.org



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CERTIFICATE

Certificate # QMS/1449

This is to certify that the facility of

TRIPLE HELIX SOLUTIONS

PL NO.19-D-II, WAPDA TOWN, LAHORE-PAKISTAN

The Facility of the below mentioned organization has been evaluated and audited against Good Manufacturing Practices (GMP), Requirement 21 CFR, PART 820 (Import Alert 76-01). The factory quality management system conforms to the requirements of GMP, FDA, See webpage link www.accessdata.fda.gov/cms_ia/importalert_224.html.

Products: Surgical and Dental Instruments.

This assessment exercise was carried with all due care on the request of manufacturer, though regular conformance to all the regulatory requirements is the sole responsibility of manufacturer. QMSCI is not affiliated with FDA USA.



Business Manager:

Issue Date: 06-03-2021

Expiry Date: 05-03-2022

To verify the validity of Certificate, please visit www.qmsci.org

R01



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This document is issued by QMSCI subject to its Certification Terms and Conditions accessible from www.qmsci.org
Consideration is drawn to the limitations of liability, indemnification and jurisdictional issues established therein.
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and delinquents may be prosecuted to fullest extent of law.

CERTIFICATE

GMP

APPROVED

Registration No: QMS/1449

THIS IS TO CERTIFY THAT

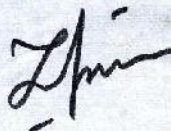
TRIPLE HELIX SOLUTIONS

PL NO. 19-D- II, WAPDA TOWN, LAHORE -PAKISTAN

IS INDIGENOUS MANUFACTURER OF
SURGICAL AND DENTAL INSTRUMENTS

The facility of the below mentioned organization has been evaluated and audited against Good Manufacturing Practices (GMP), Requirement 21 CFR, PART 820 (Import Alert 76-01), FDA, USA. The factory quality management system conforms to the requirements of GMP, FDA, USA.

WHILE ALL DUE CARE AND SKILL WAS EXERCISE IN CARRYING OUT THIS ASSESSMENT, HOWEVER REGULAR CONFORMANCE TO ALL THE REGULATORY REQUIREMENTS IS THE SOLE RESPONSIBILITY OF THE MANUFACTURER. THIS IS NOT A LEGAL DOCUMENT AND CANNOT BE USED AS SUCH



SCHEME MANAGER

ISSUE DATE: 06-03-2016

EXPIRY DATE: 05-03-2017

NUMBER OF SITES: SINGLE SITE (01)
REMAINS VALID SUBJECT TO SATISFACTORY SURVEILLANCE AUDIT.
TO VERIFY THE VALIDITY OF THIS CERTIFICATE, PLEASE VISIT: www.qmsci.org



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CERTIFICATE GMP

Registration No: QMS/1449

THIS IS TO CERTIFY THAT

TRIPLE HELIX SOLUTIONS

PL NO. 19-D- II, WAPDA TOWN, LAHORE -PAKISTAN

**IS INDIGENOUS MANUFACTURER OF
SURGICAL AND DENTAL INSTRUMENTS**

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SCHEME MANAGER

ISSUE DATE: 06-03-2017
EXPIRY DATE: 05-03-2018

NUMBER OF SITES: SINGLE SITE (01)
REMAINS VALID SUBJECT TO SATISFACTORY SURVEILLANCE AUDIT.
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Registration No: QMS/1449

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PL NO. 19-D- II, WAPDA TOWN, LAHORE -PAKISTAN

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SURGICAL AND DENTAL INSTRUMENTS

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WHILE ALL DUE CARE AND SKILL WAS EXERCISE IN CARRYING OUT THIS ASSESSMENT, HOWEVER REGULAR CONFORMANCE TO ALL THE REGULATORY REQUIREMENTS IS THE SOLE RESPONSIBILITY OF THE MANUFACTURER. THIS IS NOT A LEGAL DOCUMENT AND CANNOT BE USED AS SUCH


SCHEME MANAGER

ISSUE DATE: 06-03-2018
EXPIRY DATE: 05-03-2019

NUMBER OF SITES: SINGLE SITE (01)
REMAINS VALID SUBJECT TO SATISFACTORY SURVEILLANCE AUDIT.
TO VERIFY THE VALIDITY OF THIS CERTIFICATE, PLEASE VISIT: www.qmsci.org



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Unauthorized modification, imitation or misrepresentation of the content or appearance of this document is unlawful
and delinquents may be prosecuted to fullest extent of law.

CERTIFICATE



Dynamex Certification Services certify that

Triple Helix Solutions

Registration No. DCS/1957-B

Address to which this certificate refers:

19-D-II Wapda Town, Lahore - Pakistan.

Approved Scope to which this certificate refers:

"Manufacture of Surgical, Dental & Ophthalmic Instruments"

has been evaluated and found to meet the requirements of

ISO 13485:2016

CHAIRMAN

SCHEME MANAGER

Certificate Issue Date: 16 May, 2022

Certificate Expiry Date: 15 May, 2023

Date of Initial Registration: 16 May, 2022

Re-assessment Date: 15 May, 2025

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

www.dynamexcertification.org



CE Compliance Certificate



Application of Medical Device Regulation MDR 2017/ 745 for Class I Medical Devices.

This is certify that the products submitted are:

MEDICAL DEVICES CLASS I
(Re-Usable Surgical, Dental & Ophthalmic Instruments)
Registration no DCS/12118825119-A

Manufactured By:

Triple Helix Solutions
19-D-II Wapda Town, Lahore – Pakistan.

Comply with the applicable requirements of the MDR 2017/ 745, The Technical file of the devices have been assessed, including the EC declaration of conformity according to the Annex IV confirming that the medical devices are fulfilling the applicable requirements of MDR 2017/745.

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.

CHAIRMAN

SCHEME MANAGER

Certificate Issue Date: May 13, 2022

Certificate Expiry Date: May 12, 2023

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

www.dynamexcertification.org



CERTIFICATE



Dynamex Certification Services certify that

Triple Helix Solutions

Registration No. DCS/1957-A

Address to which this certificate refers:

19-D-II Wapda Town, Lahore - Pakistan.

Approved Scope to which this certificate refers:

“Manufacture of Surgical, Dental, Ophthalmic, Veterinary, Manicure & Pedicure Instruments”

has been evaluated and found to meet the requirements of

ISO 9001:2015

CHAIRMAN

SCHEME MANAGER

Certificate Issue Date: 16 May, 2022

Certificate Expiry Date: 15 May, 2023

Date of Initial Registration: 16 May, 2022

Re-assessment Date: 15 May, 2025

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

www.dynamexcertification.org



Certificate of Registration



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

TRIPLE HELIX SOLUTIONS

Registration No.: QAIC / PK / 2544 - 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 9001:2008.

Address to which this Certificate refers:

PL No. 19-D-II, Wapda Town, Lahore - Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Surgical, Dental, Veterinary, Manicure & Pedicure Instruments

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

Certificate Issue Date : 20th March 2017 - Certificate Expiry Date : 17th March 2018
Date of Initial Registration : 18th March 2016 - Re-Certification Before : 15th September 2018

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





CERTIFICATE OF COMPLIANCE

Certificate # DCS/9904133

This is to certify that

TRIPLE HELIX SOLUTIONS

PL NO, 19-D-II, WAPDA TOWN, LAHORE-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 Medicines and Healthcare Products Regulatory Agency (MHRA) vide reference CA016398.

PRODUCTS

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

AUTHORISED EU REPRESENTATIVE:

Mr. Abdul Razzaq
HDJ Ltd
13 Churchfields avenue
Feltham , Middx, London
TW13 5PB
United Kingdom

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: 03-03-2020

Expiry Date: 02-03-2021

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

R01



CERTIFICATE



Registration No. DCS/ 9904133

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:

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

Manufactured By:

TRIPLE HELIX SOLUTIONS

PL No. 19-D-II, Wapda Town, Lahore-Pakistan.

Comply with the applicable requirements of the Directive 93/42/EEC as updated directive 2007/47/EC for Class I Medical Devices and company is registered with Medicines and Healthcare Products Regulatory Agency (MHRA) UK (Ref: AC20160306007)

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

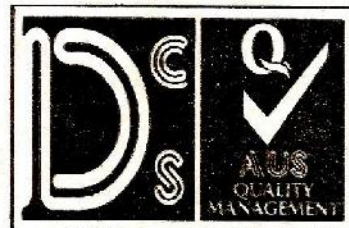
CHAIRMAN

Issue Date: March 18th, 2017

SCHEME MANAGER

Expiry Date: March 3rd, 2018

www.dynamexcertainment.org



Certificate of Registration



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

TRIPLE HELIX SOLUTIONS

Registration No.: QAIC / PK / 2544 - 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 13485:2003 & ISO 13485:2012.

Address to which this Certificate refers:

PL No. 19-D-II, Wapda Town, Lahore - Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Inert Surgical and Dental Instruments

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

Certificate Issue Date : 20th March 2017 - Certificate Expiry Date : 17th March 2018
Date of Initial Registration : 18th March 2016 - Re-Certification Before : 17th March 2019

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



Certificate of Registration



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

TRIPLE HELIX SOLUTIONS

Registration No.: QAIC / PK / 2544 - 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 13485:2003 & ISO 13485:2012.

Address to which this Certificate refers:

PL No. 19-D-II, Wapda Town, Lahore - Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Inert 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 : 6th April 2018 - Certificate Renewal Before : 17th March 2019
Date of Initial Registration : 18th March 2016 - Re-Certification Before : 17th March 2019

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



Certificate of Registration



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

TRIPLE HELIX SOLUTIONS

Registration No.: QAIC / PK / 2544 - 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:

PL No. 19-D-II, Wapda Town, Lahore - 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: 25th April 2019 - Certificate Renewal Before: 17th March 2020
Date of Initial Registration: 18th March 2016 - Re-Certification Before: 17th March 2022

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 1AP



Certificate of Registration



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

TRIPLE HELIX SOLUTIONS

Registration No.: QAIC / PK / 2544 - 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:

PL No. 19-D-II, Wapda Town, Lahore - 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: 18th March 2020 - Certificate Renewal Before: 17th March 2021
Date of Initial Registration: 18th March 2016 - Re-Certification Before: 17th March 2022

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



Certificate of Registration



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

TRIPLE HELIX SOLUTIONS

Registration No.: QAIC / PK / 2544 - 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:

PL No. 19-D-II, Wapda Town, Lahore - Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Surgical, Dental, Veterinary, Manicure & Pedicure Instruments

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

Certificate Issue Date : 6th April 2018 - Certificate Renewal Before : 17th March 2019
Date of Initial Registration : 18th March 2016 - Re-Certification Before : 17th March 2019

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



Certificate of Registration



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

TRIPLE HELIX SOLUTIONS

Registration No.: QAIC / PK / 2544 - 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:

PL No. 19-D-II, Wapda Town, Lahore - Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Surgical, Dental, Veterinary, Manicure & 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: 18th March 2020 - Certificate Renewal Before: 17th March 2021
Date of Initial Registration: 18th March 2016 - Re-Certification Before: 17th March 2022

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



Certificate of Registration



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

TRIPLE HELIX SOLUTIONS

Registration No.: QAIC / PK / 2544 - A

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Address to which this Certificate refers:

PL No. 19-D-II, Wapda Town, Lahore - Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Surgical, Dental, Veterinary, Manicure & 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: 25th April 2019 - Certificate Renewal Before: 17th March 2020
Date of Initial Registration: 18th March 2016 - Re-Certification Before: 17th March 2022

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
Tel: 01642 662222



Certificate of Registration



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

TRIPLE HELIX SOLUTIONS

Registration No.: QAIC / PK / 2544 - 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 13485:2003 & ISO 13485:2012.

Address to which this Certificate refers:

PL No. 19-D-II, Wapda Town, Lahore - Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Inert Surgical and Dental Instruments

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

Certificate Issue Date : 18th March 2016 - Certificate Expiry Date : 3rd March 2017
Date of Initial Registration : 18th March 2016 - Re-Certification Before : 17th March 2019

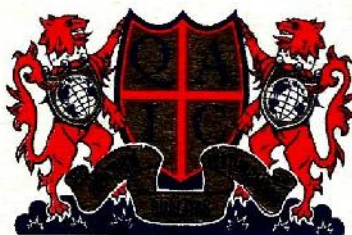
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QA INTERNATIONAL

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



Certificate of Registration



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Registration No.: QAIC / PK / 2544 - A

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Address to which this Certificate refers:

PL No. 19-D-II, Wapda Town, Lahore - Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Surgical, Dental, Veterinary, Manicure & Pedicure Instruments

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

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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



CERTIFICATE



Registration No. DCS/ 9904133

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:

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

Manufactured By:

TRIPLE HELIX SOLUTIONS
PL No. 19-D-II, Wapda Town, Lahore-Pakistan.

Comply with the applicable requirements of the Directive 93/42/EEC as updated directive
2007/47/EC for Class I Medical Devices and company is registered with Medicines and
Healthcare Products Regulatory Agency (MHRA) UK (Ref: AC20160306007)

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

Issue Date: March 18th, 2019

SCHEME MANAGER

Expiry Date: March 3rd, 2020



CERTIFICATE



Registration No. DCS/ 9904133

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:

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

Manufactured By:

TRIPLE HELIX SOLUTIONS
PL No. 19-D-II, Wapda Town, Lahore-Pakistan.

Comply with the applicable requirements of the Directive 93/42/EEC as updated directive
2007/47/EC for Class I Medical Devices and company is registered with Medicines and
Healthcare Products Regulatory Agency (MHRA) UK (Ref: AC20160306007)

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

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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

Issue Date: March 18th, 2018

SCHEME MANAGER

Expiry Date: March 3rd, 2019



CERTIFICATE



Registration No. DCS/ 9904133

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:

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

Manufactured By:

TRIPLE HELIX SOLUTIONS
PL No. 19-D-II, Wapda Town, Lahore-Pakistan.

Comply with the applicable requirements of the Directive 93/42/EEC as updated directive 2007/47/EC for Class I Medical Devices and company is registered with Medicines and Healthcare Products Regulatory Agency (MHRA) UK (Ref: AC20160306007)

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

Issue Date: March 18th, 2016

SCHEME MANAGER

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