IBC CERTIFICATE OF REGISTRATION

CE

CERTIFICATE # IBC 02105066

This is to certify that

Businessmed Instruments

Jammu Road Talwara Mughlan, Sialkot - 51310 - Pakistan.

Has been assessed for applicable requirements of Directive 93/42/EEC as updated 2007/47/EC for Class I – Reusable Medical devices (Non-Active/Non-Sterilized/Non-Measuring) and found to meet the requirements of Medical Device Directive satisfactorily and is registered with Sweden Medical Products Agency (Läkemedelsverket) with reference number 6.6.1-2021-38525.

Businessmed Instruments comply with the mentioned standards and the status of Sweden`s Competent Authority remains legible until compliance and successful surveillance. Manufacturer of a medical device is responsible to meet the applicable requirements in the Medical Devices Act (1993:584) and the Swedish Medicine Agency`s Regulations, LVFS 2003:11 or LVFS 2001:7. This assessment exercise was carried with all due care though conformance verification practices and all the regulatory requirement is the sole responsibility of manufacturer.

EU Authorized Representative
IBC - Sweden
Norsborg, Stockholm-Sweden
info@ibcsweden.eu

Active Certification:	06-05-2021 to 05-05-2022
First Surveillance:	05-05-2022
Second Surveillance:	04-05-2023

Certification Cycle

Issue Date: 06-05-2021 Expiry Date: 03-05-2024

Remains valid subject to satisfactorily surveillance audit

Digitally signed by Iarovoi Petru
Date: 2021.06.25 15:00:36 EEST
Reason: MoldSign Signature
Location: Moldova

881014-6707

Bolagsverket LÄKEMEDELSVERKET MEDICAL PRODUCTS AGENCY

CERTIFICATE OF REGISTRATION

Annex A
Authorized Representative Appointment

The Product Groups mentioned in this annex are included along with variants.

Product Name	Medical Device Classification
Scissors	MDD Class I
Needle Holders	MDD Class I
Hemostats	MDD Class I
Rectal Specula	MDD Class I
Speculums	MDD Class I
Nasal Speculums	MDD Class I
Vaginal Speculum	MDD Class I
Laryngoscopes	MDD Class I
Otoscope	MDD Class I
Ophthalmoscope	MDD Class I
Dermatoscope	MDD Class I
Scalpel & Scalpel Handles & Knives	MDD Class I
Grasping Forceps	MDD Class I
Scoops & Hooks	MDD Class I
Bone Curettes	MDD Class I
Curettes	MDD Class I
Cannulas & Suction Tubes	MDD Class I
Dilators & Probes	MDD Class I
Applicators	MDD Class I
Handheld Surgical Retractors	MDD Class I
Retractors	MDD Class I
Spatulas, Spreaders and depressors	MDD Class I
Hammers & Mallets	MDD Class I
Amputation Saw	MDD Class I
Chisels, Gouges & Osteotomes	MDD Class I

IBC CERTIFICATE OF REGISTRATION

Annex A

Authorized Representative Appointment

The Product Groups mentioned in this annex are included along with variants

Product Name	Medical Device Classification
Dental Files / Rasp	MDD Class I
Bone files / Rasps	MDD Class I
Carvers	MDD Class I
Hoes	MDD Class I
Syringes	MDD Class I
Orthodontic Cutters	MDD Class I
Articulators	MDD Class I
Dental Amalgam Gun	MDD Class I
Bone Cutters	MDD Class I
Periotome	MDD Class I
Bone Levers/Elevator	MDD Class I
Septum Elevator	MDD Class I
Skin hook	MDD Class I
Gingival cord packers	MDD Class I
Orthodontic metal band pushers	MDD Class I
Forceps	MDD Class I
Bone Holding Forceps	MDD Class I
Wire Cutting Pliers	MDD Class I
Rubber dam punches	MDD Class I
Endodontic Pluggers	MDD Class I
Orthodontic ligature directors / tuckers	MDD Class I
Self-retaining retractor	MDD Class I
Laryngoscope Blade	MDD Class I
Tweezer	MDD Class I
ENT Diagnostic set	MDD Class I

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

2021-05-06 Diarienummer: 6.6.1-2021-38525

Registreringsbekräftelse / Confirmation of registration

Företagsnamn / Company name:	IBC - Sweden
Organisationsnummer / Company registration number:	19881014-6707
Utdelningsadress / Address:	Sankt Mikaels väg 2 14564 Norsborg Stockholm Sverige
Eudamed-registreringsnummer / SRN:	SE-AR-000001625

Registrering enligt förordning (EU) 2017/745 (MDR) om medicintekniska produkter, förordning (EU) 2017/746 (IVDR) om medicintekniska produkter för in vitro-diagnostik, Läkemedelsverkets föreskrifter (LVFS 2003:11) om medicintekniska produkter, Läkemedelsverkets föreskrifter (LVFS 2001:5) om aktiva medicintekniska produkter för implantation och/eller Läkemedelsverkets föreskrifter (LVFS 2001:7) om medicintekniska produkter för in vitro-diagnostik

IBC - Sweden intygar i och med att de registrerar sin verksamhet hos Läkemedelsverket att de fullgör sina skyldigheter i enlighet med tillämpliga krav i gällande förordning(ar)/föreskrift(er).

Registreringen avser roll: Auktoriserad representant för tillverkare av CE-märkta produkter

Registration according to Regulation (EU) 2017/745 (MDR) on medical devices, Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices, the Swedish Medical Products Agency's Regulations (LVFS 2003:11) on medical devices, the Swedish Medical Products Agency's Regulations (LVFS 2001:5) on active implantable medical devices and/or the Swedish Medical Products Agency's Regulations (LVFS 2001:7) on in vitro diagnostic medical devices

IBC - Sweden declares by registering their business at the Swedish Medical Products Agency that they fulfil their obligations in accordance with applicable requirements in existing Regulation(s).

The registration relates to actor role: Authorised representative for manufacturer of CE marked devices

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0) 18 17 46 00 Fax: +46 (0) 18 50 31 15
Webbplats: www.lakemedelsverket.se E-post: registrator@lakemedelsverket.se

Produkter, Auktoriserad representant / Devices, Authorised representative

Produktkategori / Category	Riskklass / Risk class	Antal produkter / Number of devices
L: Reusable surgical instruments	MDD klass I	100

Tillverkare som verksamheten representerar / Manufacturer(s) that the authorised representative act on behalf of

Tillverkarens namn / Manufacturer name	Land / Country	e-post till tillverkaren / e-mail to the manufacturer
BUSINESSMED INSTRUMENTS	Pakistan	euprrc@gmail.com

Certificate of Registration

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

Businessmed Instruments

Registration No.: QAIC / PK / 2981 - 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:

Jammu Road, Talwara Mughlan, Sialkot- 51310- Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Non-Active Surgical, Dental and Orthodontic 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: *4th January 2019* - **Certificate Renewal Before**: *3rd January 2020*
Date of Initial Registration: *4th January 2019* - **Re-Certification Before**: *3rd January 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 4GG