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<br>14564 Norsborg Stockholm<br>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

Digitally signed by Iarovoi Petru
Date: 2021.06.24 17:18:07 EEST
Reason: MoldSign Signature
Location: Moldova

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 |

# 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

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 |

Medicines & Healthcare products
Regulatory Agency

MHRA

**Our Ref: CA017187**


Mr. Abdul Razzaq
**HDJ Ltd**
13 Churchfields Avenue
Hanworth
Feltham, London
Middlesex
TW13 5PB



**MHRA**

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom


**08 January 2019**

Dear Mr. Razzaq

**MEDICAL DEVICES REGULATIONS 2002: REGULATION 19**
**Registration of Persons Placing General Medical Devices on the Market**

Thank you for informing the Competent Authority of the details of ***Manufacturers*** **Name:- Businessmed Instruments** located at **Manufacturers Address:- Jammu Road, Talwara Mughlan Sialkot Pakistan 51310** for whom you are acting as the authorised representative and for supplying the medical device information.

**Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation, certifcation or approval by the UK Competent Authority.**

Your registration is based upon your declaration on the RG2 form and means that:

**For Manufacturers of Class I medical devices, Assemblers, and Sterilisers**

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

**For Manufacturers of Custom-made devices and Custom Made Active Implantable**

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

**If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.**

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

**Please inform us of the following chargable changes:**

- the company information e.g. name and address
- additional generic groups of devices (not individual products within an existing generic group)
- Change of authorised representative

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device from your registration record, change of contact person, postcode, telephone number and/or email address, for which payment of our statutory fee does not apply. Though, you are required to provide these non-chargeable changes in writing we will not provide an updated letter of registration. As the updated information does not affect your regulatory obligations or the information published on our Public Access Registration Database (PARD).

Medicines & Healthcare products
Regulatory Agency

MHRA

Thank you for registering the following generic groups of devices:

***Class I Devices:***

***Dental Instruments (Re-Usable & Non-Powered)***
***Handheld Dental Mirrors And Accessories***
***Laryngoscopes/Otoscopes And Accessories***
***Eye Specula***
***Surgical Instruments (Re-Usable And Non-Powered)***
***Surgical Instrument Accessories***
***Vaginal Specula (reuseable devices)***
***Nasal Speculum***

***Custom Made Devices:***

***None***

***Products Covered By Article 12:***

***None***

**Confidentiality**

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect In Vitro Diagnostic devices registration, which remain confidentiality under Article 19 of the In Vitro Diagnostic Directive 98/79EC.

**If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.**

**Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.**

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. * REPUBLICA MOLDOVA mun. CHIȘINĂU * IDNO 1004600013854 Sogno S.R.L.