

Medicines & Healthcare products Regulatory Agency

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TSI Quality Certification International Limited Suite 2A Blackthorn House St. Pauls Square Birmingham Birmingham B3 1RL England, United Kingdom

04 July 2022

Dear Laeeq Khan

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **02 July 2022** has been reviewed:

Application reference: 2022070201268788

Manufacturer organisation: System of Quality International Co.

Address:

Rehmat Elahi Building, Kashmir Road, Street Latif Abad,

Sialkot 51310 Pakistan

Manufacturer registration status: Registered

Device(s):

GMDN Code & Term	Status	Comment
33209 - Orthodontic pliers	Registered	

GMDN Code & Term	Status	Comment
31776 - Dental mirror, reusable	Registered	
12235 - Scalpel handle, reusable	Registered	
35320 - Manual dental scaler, reusable	Registered	
11791 - Dressing/utility forceps, scissors-like, reusable	Registered	
64314 - Dental elevator, sinus lift	Registered	
16480 - Dental elevator, tooth/root	Registered	
44828 - Dental cheek retractor, professional, reusable	Registered	
63854 - Mouth gag support, reusable	Registered	
35085 - Mouth gag, adjustable, reusable	Registered	
16197 - Mouth gag, non-adjustable	Registered	
31813 - Dental articulation paper forceps	Registered	
31814 - Dental dressing forceps, reusable	Registered	

GMDN Code & Term	Status	Comment
38727 - General-purpose surgical scissors, reusable	Registered	
13481 - Bandage scissors, reusable	Registered	
46830 - Laryngoscope handle, reusable	Registered	
46827 - Laryngoscope blade, reusable	Registered	
35352 - Vaginal speculum, reusable	Registered	
42500 - Dressing/utility forceps, tweezers-like, reusable	Registered	
35350 - Nasal speculum, reusable	Registered	
33433 - ENT probe, reusable	Registered	
45003 - ENT suction dissector	Registered	
15712 - Rubber dam clamp	Registered	
35851 - Rubber dam clamp forceps	Registered	
35812 - Dental explorer	Registered	

GMDN Code & Term	Status	Comment
31801 - Orthodontic metal band pusher	Registered	
35970 - Dental irrigation/aspiration syringe	Registered	
35850 - Dental impression tray, reusable	Registered	
12143 - Instrument tray, reusable	Registered	
32874 - Wire holding/twisting pliers	Registered	
31822 - Dental surgical scissors	Registered	
33965 - Episiotomy scissors, reusable	Registered	
35328 - Gynaecological scissors, reusable	Registered	
13496 - Neurosurgical scissors	Registered	
63479 - Ophthalmic strabismus scissors	Registered	
32853 - Orthopaedic joint/limb rongeur	Registered	
32850 - Orthopaedic knife	Registered	

GMDN Code & Term	Status	Comment
32526 - Tuning fork	Registered	
33542 - Bone hook	Registered	
33395 - Ear speculum, reusable	Registered	
31335 - Bone curette, reusable	Registered	
63659 - Tongue depressor, examination, reusable	Registered	
10201 - Dental articulator	Registered	
43469 - Nail extraction forceps	Registered	
38812 - Nail scissors, reusable	Registered	
44539 - Surgical flat-nosed pliers	Registered	
31848 - Periodontal probe, reusable	Registered	
14066 - Tongue depressor, surgical	Registered	
32382 - Manual scalpel blade, reusable	Registered	

GMDN Code & Term	Status	Comment
36293 - Abdominal/intestinal spatula	Registered	
38530 - Dental spatula, reusable	Registered	
39610 - General-purpose surgical spatula	Registered	
44887 - Dental osteotome	Registered	
35559 - Bone file/rasp, manual, reusable	Registered	
35296 - Nasal file/rasp	Registered	
32885 - Wire cutter	Registered	
16224 - Suture cutter, reusable	Registered	
16520 - Tonsil scissors	Registered	
15713 - Dental rongeur	Registered	
42893 - General-purpose bowl, reusable	Registered	
44821 - Washbasin	Registered	

GMDN Code & Term	Status	Comment
12507 - Medicine tray	Registered	

Please note this letter does not represent any form of <u>accreditation</u>, <u>certification or approval</u> by the UK Competent Authority.

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 UKCA or CE marked devices that do not comply with the regulations.

Please inform us of the following chargeable changes:

- 1. company/organisation information e.g. name and address
- 2. additional devices (GMDN code or term)

Please also use the Devices Online Registration Database (DORS) to tell us of the following changes e.g. removal/discontinuation of a device (GMDN) or product from your registration record, change of contact person, telephone number and/or email address, for which payment of our statutory fee does not apply.

Please note that the name and address of manufacturer, UK Responsible Person or Authorised Representative (Northern Ireland only) and devices that have been registered will be published on our <u>Public Access Registration Database</u> (PARD). In vitro diagnostic medical devices registered as undergoing performance evaluation study are not published on this database.

The account number for your company/organisation is **0000025185**.

Please do not respond directly to this email address. The originating email account is not monitored.

Yours sincerely,

Ngozi Onyeukwu

Device registrations service

Mygellen.

Devices division

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