Medicines & Healthcare products Regulatory Agency

10 South Colonnade Canary Wharf London E14 4PU United Kingdom

gov.uk/mhra

OXIS INTERNATIONAL LTD 4 Latchetts, Burgess Hill RH15 0YU England, United Kingdom

09 May 2024

Dear Muhammad Sajid

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **08 May 2024** has been reviewed:

Application reference: 2024050801360099

Manufacturer organisation: Benelux Surgical

Address:

Shahtab Garah

Sialkot 51310 Pakistan

Manufacturer registration status: Registered

Device(s):

GMDN Code & Term	Status	Comment
64144 - Acupressure applicator, reusable	Registered	

GMDN Code & Term	Status	Comment
35836 - Adenotome blade, reusable	Registered	
62260 - Air-conduction hearing aid acoustic tube	Registered	
35131 - Amputation knife	Registered	
32591 - Aneurysm clip applier	Registered	
13481 - Bandage scissors, reusable	Registered	
31335 - Bone curette, reusable	Registered	
46688 - Bone cutting forceps, reusable	Registered	
35559 - Bone file/rasp, manual, reusable	Registered	
33542 - Bone hook	Registered	
35048 - Bone lever/elevator, reusable	Registered	
35166 - Bone nail driver	Registered	
17507 - Bone tap, reusable	Registered	

GMDN Code & Term	Status	Comment
10298 - Bowl/basin stand	Registered	
45737 - Brain knife	Registered	
65073 - Cardiac transseptal access electrosurgical dilator/needle	Registered	
13708 - Cast spreader, reusable	Registered	
44445 - Cast/plaster saw	Registered	
35139 - Chisel/osteotome blade handle	Registered	
35696 - Dental amalgam carrier	Registered	
35969 - Dental anaesthesia syringe, reusable	Registered	
31776 - Dental mirror, reusable	Registered	
44887 - Dental osteotome	Registered	
15713 - Dental rongeur	Registered	
38530 - Dental spatula, reusable	Registered	

GMDN Code & Term	Status	Comment
42500 - Dressing/utility forceps, tweezers-like, reusable	Registered	
31020 - Ear snare	Registered	
31306 - Electronic oesophageal stethoscope, reusable	Registered	
13487 - Enucleation scissors, reusable	Registered	
16025 - Eye spud	Registered	
42050 - Finger protector, reusable	Registered	
35141 - Scalpel, reusable	Registered	
31822 - Dental surgical scissors	Registered	
13496 - Neurosurgical scissors	Registered	
63479 - Ophthalmic strabismus scissors, reusable	Registered	
12235 - Scalpel handle, reusable	Registered	
31814 - Dental dressing forceps, reusable	Registered	

GMDN Code & Term	Status	Comment
35851 - Rubber dam clamp forceps	Registered	
64480 - Dental implant/prosthesis handling forceps	Registered	
12726 - Suturing needle holder, reusable	Registered	
35314 - Periocular/lacrimal retractor, hand-held, reusable	Registered	
35527 - Periocular/lacrimal retractor, self-retaining	Registered	
47431 - Radial surgical retractor	Registered	
44828 - Dental cheek retractor, professional, reusable	Registered	
35812 - Dental surgical probe, reusable	Registered	
35328 - Gynaecological scissors, reusable	Registered	
38727 - General-purpose surgical scissors, reusable	Registered	
40504 - Hand-held urinal, reusable	Registered	
35320 - Manual dental scaler, reusable	Registered	

GMDN Code & Term	Status	Comment
64304 - Manual non-rotary dental instrument handle	Registered	
63414 - Mouth gag cover	Registered	
35082 - Obstetrical forceps, reusable	Registered	
11950 - Percussion hammer, manual, reusable	Registered	
66887 - Sterilization container filter, reusable	Registered	
35090 - Surgical gouge	Registered	
32312 - Surgical mallet	Registered	
33968 - Surgical screwdriver, reusable	Registered	
63659 - Tongue depressor, examination, reusable	Registered	
32526 - Tuning fork	Registered	
16480 - Dental elevator, tooth/root	Registered	
33204 - Dental matrix band retainer	Registered	

GMDN Code & Term	Status	Comment
33209 - Orthodontic pliers	Registered	
31813 - Dental articulation paper forceps	Registered	
41660 - Periodontal curette	Registered	
35850 - Dental impression tray, reusable	Registered	
46786 - Direct ophthalmoscope	Registered	
61794 - Direct otoscope/audiometer	Registered	
15076 - Rigid intubation laryngoscope, reusable	Registered	
10058 - Airway obstruction forceps	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 0000031615.

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

Yours sincerely,

Ngozi Onyeukwu

Device registrations service

Duyellen.

Devices division

Medicines and Healthcare products Regulatory Agency