Medicines & Healthcare products Regulatory Agency

10 South Colonnade Canary Wharf London E14 4PU United Kingdom

gov.uk/mhra

INSPECCO LTD 182 High Street, North Ham, London E6 1HS England, United Kingdom

08 September 2023

Dear Folk SOAY

We are pleased to confirm that the application to register or update an existing registration for the following manufacturer, which you submitted on **08 September 2023** has been reviewed:

Application reference: 2023090801319368

Manufacturer organisation: **ROCKMED INDUSTRIES**

Address:

61-B, LIAQAT ALI ROAD, S.I.E, SHAHABPURA,

Sialkot 51310 Pakistan

Manufacturer registration status: Registered

Device(s):

GMDN Code & Term	Status	Comment
35552 - Tooth extraction forceps	Registered	

GMDN Code & Term	Status	Comment
32853 - Orthopaedic joint/limb rongeur	Registered	
35970 - Dental irrigation/aspiration syringe	Registered	
16480 - Dental elevator, tooth/root	Registered	
31776 - Dental mirror, reusable	Registered	
35320 - Manual dental scaler, reusable	Registered	
62466 - Surgical soft-tissue manipulation forceps, tweezers-like, reusable	Registered	
41660 - Periodontal curette	Registered	
11289 - Dissection kit	Registered	
45414 - Liposuction system cannula, reusable	Registered	
39610 - General-purpose surgical spatula	Registered	
10201 - Dental articulator	Registered	
34961 - Towel clamp, reusable	Registered	

GMDN Code & Term	Status	Comment
38727 - General-purpose surgical scissors, reusable	Registered	
12726 - Suturing needle holder, reusable	Registered	
38168 - Periosteal elevator, reusable	Registered	
45000 - Rubber dam kit	Registered	
62477 - Dental composite resin kit	Registered	
11265 - Urethral dilator, reusable	Registered	
62605 - ENT surgical aspirator	Registered	
35559 - Bone file/rasp, manual, reusable	Registered	
12235 - Scalpel handle, reusable	Registered	
32312 - Surgical mallet	Registered	
16341 - Cast cutting shears	Registered	
44445 - Cast/plaster saw	Registered	

GMDN Code & Term	Status	Comment
31822 - Dental surgical scissors	Registered	
45182 - Self-retaining surgical retractor, reusable	Registered	
33209 - Orthodontic pliers	Registered	
32071 - Biopsy forceps cover	Registered	
35255 - Proctoscope, reusable	Registered	
46751 - Bone holding forceps	Registered	
44887 - Dental osteotome	Registered	
18129 - Manual bone mill	Registered	
32390 - Fluted surgical drill bit, reusable	Registered	
33968 - Surgical screwdriver, reusable	Registered	
45918 - Hand-held surgical retractor, reusable	Registered	
64006 - Bone file/rasp, reciprocating, reusable	Registered	

GMDN Code & Term	Status	Comment
64337 - Bone-coring punch, reusable	Registered	
13730 - Device sterilization/disinfection container, reusable	Registered	
42893 - General-purpose bowl, reusable	Registered	
61457 - Dental examination kit	Registered	
35352 - Vaginal speculum, reusable	Registered	
35812 - Dental surgical probe, reusable	Registered	
35851 - Rubber dam clamp forceps	Registered	
65582 - Instrument tray cover, reusable	Registered	
35850 - Dental impression tray, reusable	Registered	
62727 - Skin marking guide, reusable	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</u> <u>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 0000029588.

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

Yours sincerely,

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Device registrations service

hongellen.

Devices division

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