



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

## Compliance Management Solutions

for approval to supply

### Compliance Management Solutions - Orthopaedic prosthesis implantation instrument, reusable

ARTG Identifier	393360
ARTG Start Date	3/08/2022
Product Category	Medical Device Included Class IIa
GMDN	13180
GMDN Term	Orthopaedic prosthesis implantation instrument, reusable
Intended Purpose	SAYAN surgical bone cutting tools are used for bone reshaping, tapping, perforation, grating, drilling and reaming during surgical interventions.

Manufacturer Details	Address	Certificate number(s)
Sayan Tibbi Aletler Pazarlama San ve Tic Ltd Sti	Kemalpasa Mahallesi 7110/2 Sokak No 4 Bornova , Izmir , 35060 Turkey	DV-2022-MC-10277-1

#### ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

#### Products Covered by This Entry

##### 1. Orthopaedic prosthesis implantation instrument, reusable

#### Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
PO Box 100, Woden ACT 2606 Australia  
Phone: 1800 020 653  
Email: [info@tga.gov.au](mailto:info@tga.gov.au)

ARTG Identifier: 393360  
ARTG Start Date: 3/08/2022



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

<b>Record Summary</b>	393360	Compliance Management Solutions - Orthopaedic prosthesis implantation instrument, reusable
<b>Sponsor</b>	Compliance Management Solutions	
<b>Therapeutic Type</b>	Medical Device	
<b>Product Category</b>	Included Class IIa	
<b>ARTG Start Date</b>	3/08/2022	
<b>Postal Address</b>	1B 85 Curzon Street, NORTH MELBOURNE, VIC, 3051 Australia	
<b>Billing Address</b>	1B 85 Curzon Street, NORTH MELBOURNE, VIC, 3051 Australia	
<b>Product Type</b>	Medical Device - Class IIa - Included	
<b>Status</b>	Active	
<b>Approval Area</b>	Medical Devices	

**Conditions**

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

**Manufacturers**

Name	Address	Certificate number(s)
Sayan Tibbi Aletler Pazarlama San ve Tic Ltd Sti	Kemalpasa Mahallesi 7110/2 Sokak No 4 Bornova , Izmir , 35060 Turkey	DV-2022-MC-10277-1

**Products**

**1 . Orthopaedic prosthesis implantation instrument, reusable**

<b>Product Type</b>	Single Device Product	<b>Status</b>	Current
		<b>Effective Date</b>	3/08/2022
<b>GMDN</b>	13180 Orthopaedic prosthesis implantation instrument, reusable		
<b>Functional Description</b>	Not included on record		
<b>Intended Purpose</b>	SAYAN surgical bone cutting tools are used for bone reshaping, tapping, perforation, grating, drilling and reaming during surgical interventions.		

**Variant Information**

**Device Information**

09 Reusable devices

**Specific Conditions**

No Specific Conditions included on Record

Record Summary