

No. of Certificate : 20150059680

Date : 2015/04/06

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea

Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. : 3072)

SURGIDENT

#210, Woolim Lions Valley, 27, Dunchon-daero457beon-gil ,
Jungwon-gu,Seongnam-si,Gyeonggi-do,Korea

Product-License No.	Classification
Gyeongin 14-384	Trephine instrument, manually-operated, reusable
Gyeongin 14-385	implant, endosseous, screw driver
Gyeongin 14-429	Trephine instrument, manually-operated, reusable
Gyeongin 14-606	implant, endosseous, hand instrument
Gyeongin 14-607	Trephine instrument, manually-operated, reusable

※ Attached : List of Product Classification and Model

o Do the facilities and operations conform to KGMP as recommended by the Ministry of Food and Drug Safety?

☒ Yes

☐ No

To geon chang

Director of General Services Division
Gyeongin Regional Food & Drug
Administration

No. of Certificate : 20150059680

Date : 2015/04/06

Product License No. : Gyeongin 14-384 (2015/02/11)

Classification : Trephine instrument, manually-operated, reusable

Model (Export Name)

- STOP DRILL KIT

Product License No. : Gyeongin 14-385 (2014/06/10)

Classification : implant, endosseous, screw driver

Model (Export Name)

- IMPLANT PROSTHETIC DRIVER KIT

Product License No. : Gyeongin 14-429 (2015/02/11)

Classification : Trephine instrument, manually-operated, reusable

Model (Export Name)

- SD Reamer Set

Product License No. : Gyeongin 14-606 (2014/11/06)

Classification : implant, endosseous, hand instrument

Model (Export Name)

- SINGLE-OUT

Product License No. : Gyeongin 14-607 (2015/02/11)

Classification : Trephine instrument, manually-operated, reusable

Model (Export Name)

- MP20

No. of Certificate : 20150059686

Date : 2015/04/06

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea

Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. : 3072)

SURGIDENT

#210, Woolim Lions Valley, 27, Dunchon-daero457beon-gil,
Jungwon-gu,Seongnam-si,Gyeonggi-do,Korea

Product-License No.	Classification
Gyeongin 13-137	Elevator, surgical, manually-operated
Gyeongin 13-238	implant, endosseous, hand instrument
Gyeongin 13-471	Abrasive device
Gyeongin 13-472	Trephine instrument, manually-operated, reusable
Gyeongin 14-159	Trephine instrument, manually-operated, reusable

※ Attached : List of Product Classification and Model

o Do the facilities and operations conform to KGMP as recommended by the Ministry of Food and Drug Safety?

☒ Yes

☐ No

To geon chang

Director of General Services Division
Gyeongin Regional Food & Drug
Administration

No. of Certificate : 20150059686

Date : 2015/04/06

Product License No. : Gyeongin 13-137 (2013/03/15)

Classification : Elevator, surgical, manually-operated

Model (Export Name)

- BASIC KIT

Product License No. : Gyeongin 13-238 (2013/05/22)

Classification : implant, endosseous, hand instrument

Model (Export Name)

- P.R.F SYSTEM

Product License No. : Gyeongin 13-471 (2015/02/11)

Classification : Abrasive device

Model (Export Name)

- Never Loss Bone Collector

Product License No. : Gyeongin 13-472 (2015/02/11)

Classification : Trephine instrument, manually-operated, reusable

Model (Export Name)

- Water Rising System

Product License No. : Gyeongin 14-159 (2015/02/11)

Classification : Trephine instrument, manually-operated, reusable

Model (Export Name)

- Easy Sinus Kit

No. of Certificate : 20150059715

Date : 2015/04/06

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea

Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. : 3072)

SURGIDENT

#210, Woolim Lions Valley, 27, Dunchon-daero457beon-gil,
Jungwon-gu,Seongnam-si,Gyeonggi-do,Korea

Product-License No.	Classification
Gyeongin 13-133	Trephine instrument, manually-operated, reusable
Gyeongin 13-134	Abrasive device
Gyeongin 13-136	Gouge, surgical, manually-operated

※ Attached : List of Product Classification and Model

o Do the facilities and operations conform to KGMP as recommended by the Ministry of Food and Drug Safety?

☒ Yes

☐ No

To geon chang

Director of General Services Division
Gyeongin Regional Food & Drug
Administration

Building #5, Gwacheon Government Complex ,
47 Gwanmoon-ro, Gwacheon-si, Gyeonggi-do, Korea,
Tel: 82-2-2110-8000, Fax: 82-2-2110-0801

No. of Certificate : 20150059715

Date : 2015/04/06

Product License No. : Gyeongin 13-133 (2015/02/11)

Classification : Trephine instrument, manually-operated, reusable

Model (Export Name)

· OSTEOTOME S-SET	· OSTEOTOME R-SET
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Product License No. : Gyeongin 13-134 (2015/02/11)

Classification : Abrasive device

Model (Export Name)

· TRIMMER KIT	· TOP-SYSTEM
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Product License No. : Gyeongin 13-136 (2013/03/15)

Classification : Gouge, surgical, manually-operated

Model (Export Name)

· SD-BONE MILL

No. of Certificate : 20150059718

Date : 2015/04/06

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea

Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. : 3072)

SURGIDENT

#210, Woolim Lions Valley, 27, Dunchon-daero457beon-gil,
Jungwon-gu,Seongnam-si,Gyeonggi-do,Korea

Product-License No.	Classification
Gyeongin 13-132	Puncture instrument, surgical, manually-operated, reusable
Gyeongin 13-133	Trephine instrument, manually-operated, reusable

※ Attached : List of Product Classification and Model

o Do the facilities and operations conform to KGMP as recommended by the Ministry of Food and Drug Safety?

☒ Yes

☐ No

To geon chang

Director of General Services Division
Gyeongin Regional Food & Drug
Administration

Building #5, Gwacheon Government Complex ,
47 Gwanmoon-ro, Gwacheon-si, Gyeonggi-do, Korea,
Tel: 82-2-2110-8000, Fax: 82-2-2110-0801

No. of Certificate : 20150059718

Date : 2015/04/06

Product License No. : Gyeongin 13-132 (2015/02/11)

Classification : Puncture instrument, surgical, manually-operated, reusable

Model (Export Name)

- | | |
|---------------------|----------------------|
| · BONE EXPANDER KIT | · BONE SPREADING KIT |
| · BONE MULTI SYSTEM | |

Product License No. : Gyeongin 13-133 (2015/02/11)

Classification : Trephine instrument, manually-operated, reusable

Model (Export Name)

- | | |
|------------|-----------------|
| · TOCA-KIT | · AQUA TOCA-KIT |
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No. of Certificate : 20150059725

Date : 2015/04/06

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea

Importing(requesting) country :

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. : 3072)

SURGIDENT

#210, Woolim Lions Valley, 27, Dunchon-daero457beon-gil,
Jungwon-gu,Seongnam-si,Gyeonggi-do,Korea

Product-License No.	Classification
Gyeongin 11-242	Surgical drill handpiece, manual
Gyeongin 13-130	Chisel, surgical, manually-operated
Gyeongin 13-131	Curette, manually-operated, reusable

※ Attached : List of Product Classification and Model

o Do the facilities and operations conform to KGMP as recommended by the Ministry of Food and Drug Safety?

☒ Yes

☐ No

To geon chang

Director of General Services Division
Gyeongin Regional Food & Drug
Administration

Building #5, Gwacheon Government Complex ,
47 Gwanmoon-ro, Gwacheon-si, Gyeonggi-do, Korea,
Tel: 82-2-2110-8000, Fax: 82-2-2110-0801

No. of Certificate : 20150059725

Date : 2015/04/06

Product License No. : Gyeongin 11-242 (2011/08/08)

Classification : Surgical drill handpiece, manual

Model (Export Name)

· SD-TORQUE

Product License No. : Gyeongin 13-130 (2013/03/14)

Classification : Chisel, surgical, manually-operated

Model (Export Name)

· RIDGE SPLIT SET

Product License No. : Gyeongin 13-131 (2015/02/11)

Classification : Curette, manually-operated, reusable

Model (Export Name)

· TOLA-KIT