NEW AGE

IMPLANTING VALUES



Cannulated Headless Screw

FDA

DRUG LICENSE INDIAN FDA

CE

CE CERTIFICATE

ISO 13485:2016 Medical Devices

ISO 13485:2016

ISO 9001:2015

ISO 9001:2015

GMP Quality

GMP QUALITY

About NewAge Medisys Limited

NewAge Medisys Limited is an ISO 13485: 2016 & CE Certified manufacturer and supplier of the widest range of surgical implants including Trauma system, Spine system, Hip system and it's instruments.

We are engaged in manufacturing and exporting of orthopaedic implants with a passion to make available best quality and précised implants to surgeons & patients.

At NewAge Medisys Limited, we don't emphasize on figures, but are devoted to continuous research & development and pledged to enforce ultra modern improvements on varieties of orthopaedic implants. Each orthopaedic implant that we manufacture is made with cutting edge technology and exceptional quality standards which are clinically proven.

We take extreme pride in our experts and dedicated team that makes sure quality is never compromised.

We are equipped with the latest automated technology CNC, VMC and Swiss-Type Sliding Head machines imported from countries like South Korea and Taiwan.

Many importers from the Middle East and Latin America sell our products under their brands. This itself is a testimony to acceptances of our core competencies in quality control, product design & development, computer aided manufacturing, prototyping and packaging.

With next generation orthopaedic implants, we are deliberately becoming a leader in the medical implants market.

WHAT MAKES US EXCEPTIONAL THAN OTHERS:

- Premium Quality.
- Maintaining exceptional Quality standards.
- Manufacturing implants with cutting edge technologies.
- Constant product innovation in design inputs.
- Commitment & determination.
- Prompt delivery.
- After-sales service.
- Easy Communication.



Certification & Inspection

Certificate of Compliance

CE

We hereby declare that the technical files of all the items in each product group complies with the requirements of the Council Directive on **Medical Device Regulation - (Council Regulation 2017/745)**

Certificate No.: CE-6961

Manufacturer

Name : NEWAGE MEDISYS LIMITED

Address : PLOT NO B 1, SURVEY NO 275, GALAXY INDUSTRIAL ESTATE, BEHIND TULSI METAL, SHAPAR VERAVAL, RAJKOT, GUJARAT – 360024, INDIA

Product : DESIGN AND DEVELOPMENT OF ORTHOPAEDIC IMPLANTS & INSTRUMENTS (more detail as per Appendix I & III)

Complies with the requirements applicable to it

The quality system file has been assessed, approved and is subject to continuous surveillance according to the Council Directive on **Medical Device Regulation -(Council Regulation 2017/745)**

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	21st April 2025
1st Surveillance Audit Due	20th April 2026
2nd Surveillance Audit Due	20th April 2027
Certificate Expiry (subject to the company maintaining its system to the required standard)	20th April 2028

Authorised Signatory

Page 1 of 4

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851



Certification & Inspection

Certificate of Registration

This is to certify that the
Quality Management System for Medical Devices
of

NEW AGE IMPLANTING VALUES

NEWAGE MEDISYS LIMITED

at

PLOT NO B 1, SURVEY NO 275, GALAXY INDUSTRIAL ESTATE, BEHIND TULSI METAL, SHAPAR VERAVAL, RAJKOT, GUJARAT – 360024, INDIA

has been independently assessed and is
compliant with the requirements of:

ISO 13485:2016

For the following scope of activities:

DESIGN AND DEVELOPMENT OF ORTHOPAEDIC IMPLANTS & INSTRUMENTS

Certificate Number: UQ - 2025042135

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	21st April 2025
1st Surveillance Audit Due	20th April 2026
2nd Surveillance Audit Due	20th April 2027
Certificate Expiry	20th April 2028

Authorised Signatory

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Company No. 11847851



Certification & Inspection

Certificate of Compliance

Certificate Number: UQ - 2025042134

This is to certify that

NEW AGE IMPLANTING VALUES

NEWAGE MEDISYS LIMITED

at

PLOT NO B 1, SURVEY NO 275, GALAXY INDUSTRIAL ESTATE, BEHIND TULSI METAL, SHAPAR VERAVAL, RAJKOT, GUJARAT – 360024, INDIA

Has successfully implemented the Quality management System and been found working satisfactorily as per the norms of **"Good Manufacturing Practice"** as laid down by **"World Health Organisation"** which has been in conformance to the requirements of

WHO-GMP

SCOPE:- DESIGN AND DEVELOPMENT OF ORTHOPAEDIC IMPLANTS & INSTRUMENTS

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced Models Products.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the WHO-GMP Guidelines
3. The certificate validity is conditioned by positive results or surveillance audits.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification	21st April 2025
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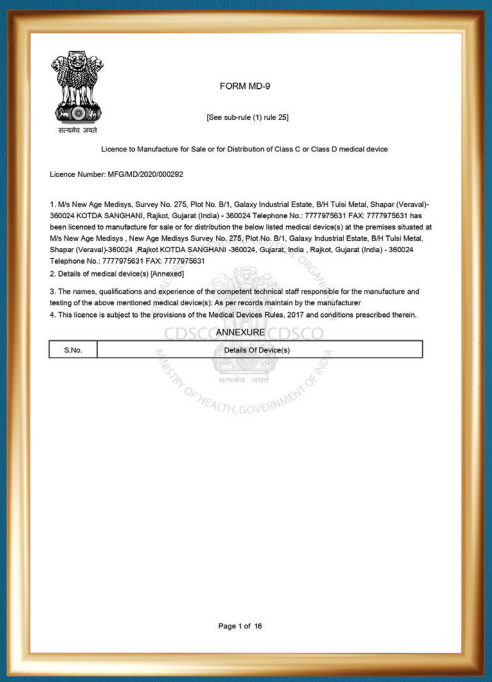


सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2020/000292

1. M/s New Age Medisys, Survey No. 275, Plot No. B/1, Galaxy Industrial Estate, B/H Tulsi Metal, Shapar (Veraval)-360024 KOTDA SANGHANI, Rajkot, Gujarat (India) - 360024 Telephone No.: 7777975631 FAX: 7777975631 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s New Age Medisys , New Age Medisys Survey, No. 275, Plot No. B/1, Galaxy Industrial Estate, B/H Tulsi Metal, Shapar (Veraval)-360024 ,Rajkot KOTDA SANGHANI -360024, Gujarat, India , Rajkot, Gujarat (India) - 360024 Telephone No.: 7777975631 FAX: 7777975631

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

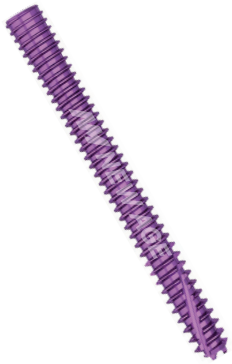
S.No.	Details Of Device(s)

Page 1 of 16

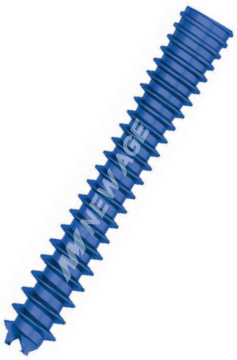
Headless Screw

3.0mm Headless Compression Screw

Length (mm)	Reference Number SS316	TIT
12mm	1761.12	2761.12
14mm	1761.14	2761.14
16mm	1761.16	2761.16
18mm	1761.18	2761.18
20mm	1761.20	2761.20
22mm	1761.22	2761.22
24mm	1761.24	2761.24
26mm	1761.26	2761.26
28mm	1761.28	2761.28
30mm	1761.30	2761.30



3.5mm Headless Compression Screw



Length (mm)	Reference Number SS316	TIT
14mm	1762.14	2762.14
16mm	1762.16	2762.16
18mm	1762.18	2762.18
20mm	1762.20	2762.20
22mm	1762.22	2762.22
24mm	1762.24	2762.24
26mm	1762.26	2762.26
28mm	1762.28	2762.28
30mm	1762.30	2762.30
32mm	1762.32	2762.32
34mm	1762.34	2762.34
36mm	1762.36	2762.36
38mm	1762.38	2762.38
40mm	1762.40	2762.40

4.0mm Headless Compression Screw



Length (mm)	Reference Number SS316	TIT
16mm	1763.16	2763.16
18mm	1763.18	2763.18
20mm	1763.20	2763.20
22mm	1763.22	2763.22
24mm	1763.24	2763.24
26mm	1763.26	2763.26
28mm	1763.28	2763.28
30mm	1763.30	2763.30
32mm	1763.32	2763.32
34mm	1763.34	2763.34
36mm	1763.36	2763.36
38mm	1763.38	2763.38
40mm	1763.40	2763.40
42mm	1763.42	2763.42
44mm	1763.44	2763.44
46mm	1763.46	2763.46
48mm	1763.48	2763.48
50mm	1763.50	2763.50
55mm	1763.55	2763.55
60mm	1763.60	2763.60

NEW AGE
IMPLANTING VALUES

4.5mm Headless Compression Screw



Length (mm)	Reference Number SS316	TIT
20mm	1764.20	2764.20
22mm	1764.22	2764.22
24mm	1764.24	2764.24
26mm	1764.26	2764.26
28mm	1764.28	2764.28
30mm	1764.30	2764.30
32mm	1764.32	2764.32
34mm	1764.34	2764.34
36mm	1764.36	2764.36
38mm	1764.38	2764.38
40mm	1764.40	2764.40
42mm	1764.42	2764.42
44mm	1764.44	2764.44
46mm	1764.46	2764.46
48mm	1764.48	2764.48
50mm	1764.50	2764.50
55mm	1764.55	2764.55
60mm	1764.60	2764.60
65mm	1764.65	2764.65
70mm	1764.70	2764.70

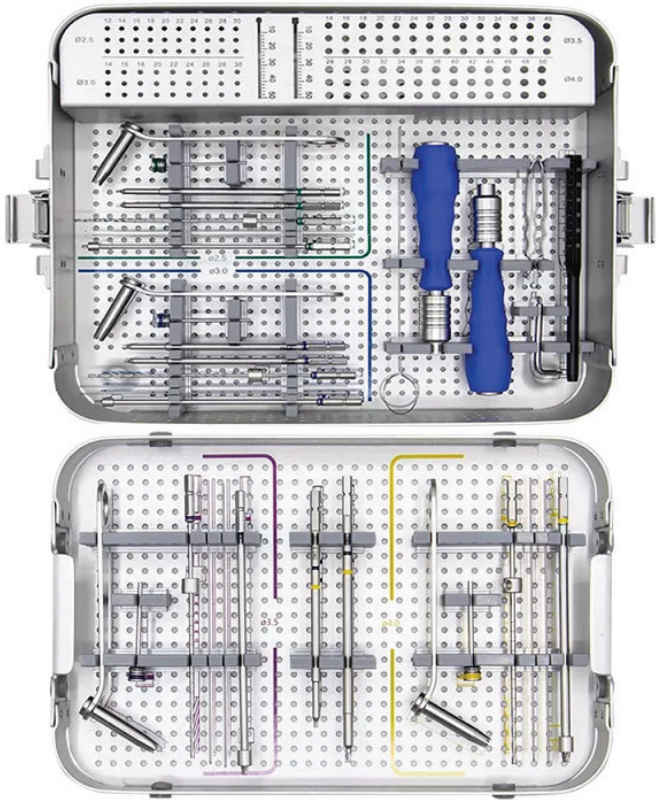
5.0mm Headless Compression Screw



Length (mm)	Reference Number SS316	TIT
20mm	1765.20	2765.20
22mm	1765.22	2765.22
24mm	1765.24	2765.24
26mm	1765.26	2765.26
28mm	1765.28	2765.28
30mm	1765.30	2765.30
32mm	1765.32	2765.32
34mm	1765.34	2765.34
36mm	1765.36	2765.36
38mm	1765.38	2765.38
40mm	1765.40	2765.40
42mm	1765.42	2765.42
44mm	1765.44	2765.44
46mm	1765.46	2765.46
48mm	1765.48	2765.48
50mm	1765.50	2765.50
55mm	1765.55	2765.55
60mm	1765.60	2765.60
65mm	1765.65	2765.65
70mm	1765.70	2765.70

Instrument Set

Cannulated Compression Headless 3.0 - 3.5 - 4.0 - 4.5mm Headless Screw Instrument Set



Code No.	Instrument Name
7006.01	Clean wire Ø1.5 x 200
7006.02	Cannulated Drill Bit Ø3.5 x Ø 1.5 x 200 with Limitator
7006.03	Cannulated Drill Bit Ø3.5 x Ø 1.5 x 200
7006.04	Ø3.5 Limitator
7006.05	Guider Wire 1.5 x 200
7006.06	Guider Wire 1.5 x 200
7006.07	Cannulated Countersink Ø5.0 x Ø1.5 x 150
7006.08	Hex Screwdriver SW3.0
7006.09	Cannulated Hex Screwdriver SW3.0
7006.10	Wire Sleeve Ø1.6
7006.11	Drill Sleeve Ø3.5
7006.12	Canuated Drill Bit Ø2.8 x Ø1.2 x 150 with Limitator
7006.13	Canuated Drill Bit Ø2.8 x Ø1.2 x 150
7006.14	Ø2.8 Limitator
7006.15	Guider Wire 1.2 x 150
7006.16	Guider Wire 1.2 x 150
7006.17	Cannulated Countersink Ø3.5 x Ø1.3 x 150
7006.18	Hex Screwdriver SW2.5
7006.19	Cannulated Hex Screwdriver SW2.5(Ø1.3)
7006.20	Wire Sleeve Ø1.3 x 3.0
7006.21	Drill Sleeve Ø2.8
7006.22	Drill Sleeve Ø2.0
7006.23	Wire Sleeve Ø1.1 x 2.0

Code No.	Instrument Name
7006.24	Canuated Drill Bit Ø2.0 x Ø1.1 x 150 with Limitator
7006.25	Canuated Drill Bit Ø2.0 x Ø1.1 x 150
7006.26	Ø2.0 Limitator
7006.27	Cannulated Hex Screwdriver SW2.0
7006.28	Hex Screwdriver SW2.0
7006.29	Guider Wire 1.0 x 150
7006.30	Guider Wire 1.0 x 150
7006.31	Guider Wire 1.0 x 150
7006.32	Guider Wire 1.0 x 150
7006.33	Cannulated Countersink Ø3.0 x Ø1.1 x 150
7006.34	Drill Sleeve Ø2.5
7006.35	Wire Sleeve Ø1.1 x 2.5
7006.36	Canuated Drill Bit Ø2.5 x Ø1.1 x 150 with Limitator
7006.37	Canuated Drill Bit Ø2.5 x Ø1.1 x 150
7006.38	Ø2.5 Limitator
7006.39	Clean Wire Ø1.2
7006.40	Depth Gague 10-60mm & 10-70mm
7006.41	Hex Key SW2.5
7006.42	Screw Holding Forcep
7006.43	Quick Coupling Handle
7006.44	Quick Coupling Handle
7006.45	Clean Wire Ø1.0

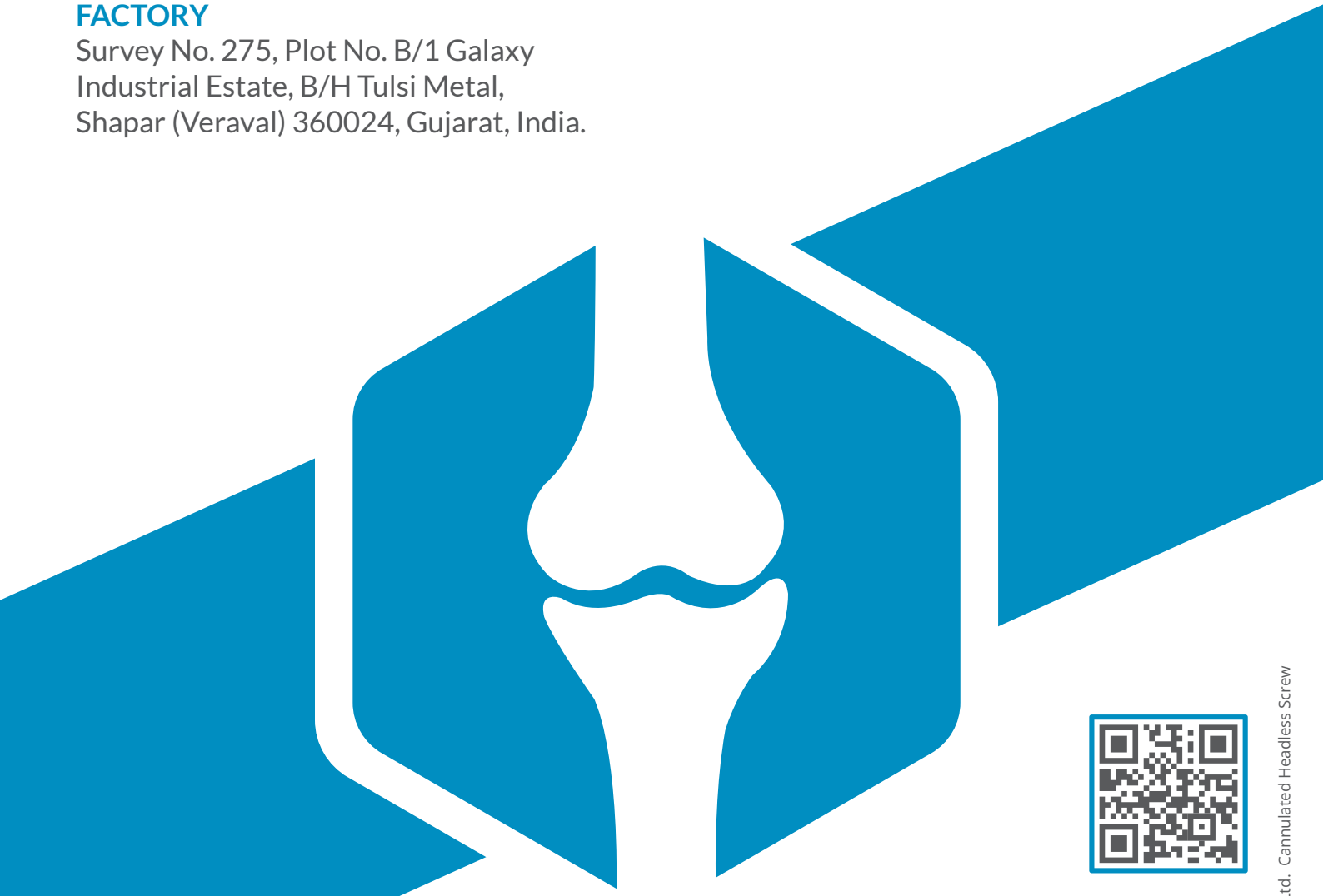
Transforming Lives or A Better Future!

Contact Us.....

HEAD OFFICE
908 & 909, RK Prime, Next to
Silver Heights, 150 ft Ring Road,
Rajkot – 360005.

MUMBAI OFFICE
Pranik Chamber, A-wing,
5th Floor- 501, Sakinaka, Andheri
East, Mumbai – 400072.

FACTORY
Survey No. 275, Plot No. B/1 Galaxy
Industrial Estate, B/H Tulsi Metal,
Shapar (Veraval) 360024, Gujarat, India.



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