



CERTIFICATE OF REGISTRATION

This certifies that:

META ERGONOMICA S.R.L.
Via Monte Nero, 19
20029 Turbigo (MI)
Italy

is registered and has listed the following medical devices with the U.S. Food and Drug Administration pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations, such registration and listing having been verified as currently effective on, and as of the date hereof, by Thema s.r.l.

Establishment Registration:
Device Classification Name:

3011922183
REMOVER, CROWN; CHISEL (OSTEOTOME) - MOTOR,
SURGICAL INSTRUMENT, AC-POWERED

Product Code:
Regulation Number:
Official Correspondent:

EIS - KDG - GEY
872.4565 - 878.4820

Itala Pardo
Via Monte Nero, 19
20029 Turbigo (MI) Italy
Phone: +39.033.1899540

And U.S. Agent:

Mauro Carichini
Mauro Carichini For Thema USA
270 Richmond Terrace, Apt R
Staten Island, NY 10301
Phone: 134.7247741 Ext 9
E-mail: info@themausa.net

Thema s.r.l. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after the issuance of this certificate. Thema s.r.l. makes no other representations or warranties, nor does this certificate make any representation or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Thema s.r.l. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39. "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its product. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding".

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Thema s.r.l. is not affiliated with the U.S. Food and Drug Administration.



Thema s.r.l. , via Saragat, 5 , 40026 Imola (BO) , Italy
Telephone +39.0542.643496 - Fax +39.0542.641833
info@thema-med.com - www.thema-med.com

Marisa Testa
CEO

Thema s.r.l.

Dated: January 31, 2019