



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 - 878.4820
Itala Pardo
Via Monte Nero, 19 20029 Turbigo
(MI) Italy Phone: +39.033.1899540
Mauro Carichini
Mauro Carichini For Thema USA
390 E 8th street, 4A
New York, NY US 10009
Phone: 347 2477419 Ext
E-mail: Info@Themausa.Net**

And U.S. Agent:

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.



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**Marisa Testa
CEO**

Thema s.r.l.
Dated: April 23, 2021