LEGHE LEGGERE LAVORATE

ICIM UNI CEI EN ISO 13485:2021 CERTIFIED MANAGEMENT SYSTEM

ICIM UNI EN ISO 9001:2015 CERTIFIED MANAGEMENT SYSTEM

FDA REGISTRATION NUMBER 3005059805

ANVISA

Parità di Genere CERTIFICAZIONE UNI/PdR 125:2022

Your Contract Manufacturer


New!
PLANT
4
PLANT
3
PLANT
2
PLANT
1

LEGHE LEGGERE LAVORATE

EXPERIENCE Leghe Leggere Lavorate is the first Italian company specialized in the production of components for orthopedic surgery (human and veterinary) and dental implantology, on behalf of third parties.

QUALITY We are the only subcontractor in Italy able to provide a 360° service which includes Design, CAD-CAM, Production, Finishing, Cleaning, Packaging in clean room and VMI System. From the idea to the delivery of the finished product, allowing our customer to choose a single-source partner in order to save time and resources. order to save time and resources.

PRECISION But how did we get here? Thanks to our passion for mechanics since 1951, in the mid-1990s we entered the medical world, facing a difficult and selective market that required investments in machines and people.In fact, we first added 5-axis milling centers to the turning machines and plastic injection molding and co-molding machines, then we completed our offer with the finishing and packaging departments in an ISO-7 clean room. Today, we boast 4 production plants employing 130 qualifiedemployees, with the aim of positioning ourselves as a leader in Europe for the production of medical devices in OEM.

2 π Radians

Discover our full-service capabilities

Leghe Leggere Lavorate, is an industry leading Contract Manufacturer that offers fully integrated medical device manufacturing capabilities.
From design and development, through the validation and production process, up to packaging and logistics.

- DESIGN
- CAD-CAM
- PRODUCTION
- FINISHING
- CLEANING
- VMI SYSTEM

Forward-thinking vision

CAD-CAM

The creation of each new medical device is processed using Cad-Cam software,starting from the 3D files supplied by customers. These software can simulate the operations of the processing phase thanks to various parameters. This allows to evaluate the most critical aspects of the processes and to define the most suitable solutions.

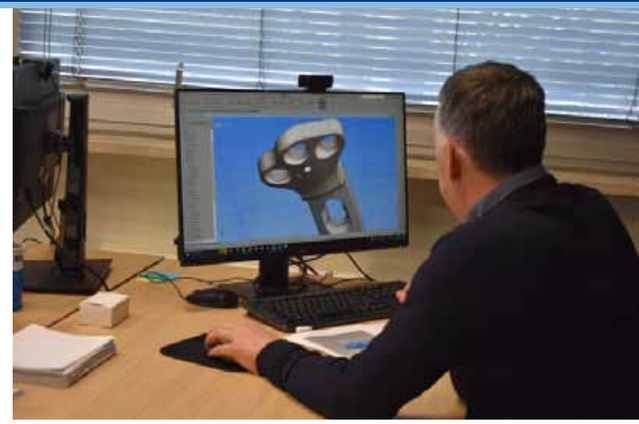
Leghe Leggere Lavorate technical department is able to study and realize any kind of piece or mechanical handling suggesting possible technical solution that, without alter the design, could reduce product costs.

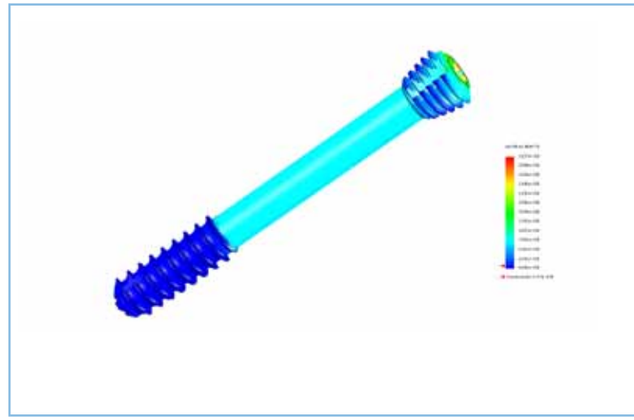
In detail:

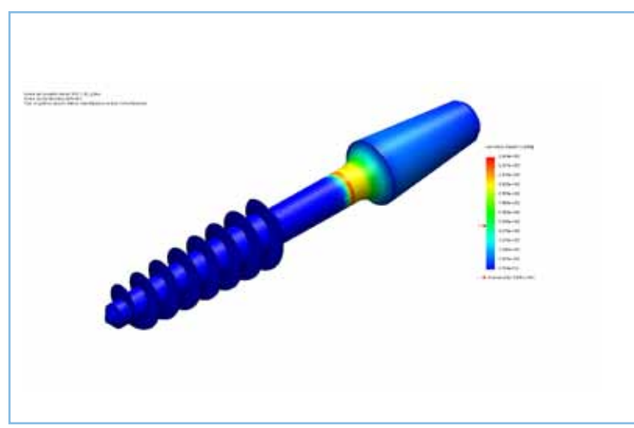
- Mechanical design
- FEM/FEA analysis
- Technical Manual
- Technical data and list of components management
- Technical 2D and 3D drawings
- Trasparency of data with a dedicated internet portal
- Static and dynamic tests

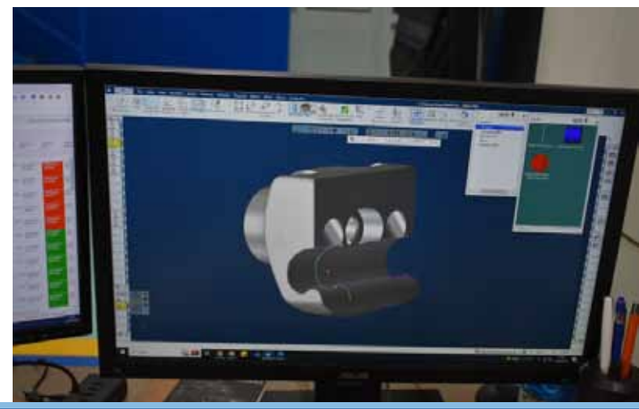
DESIGN

- Pre tendering
- Patent analysis
- Preliminary risk analysis
- Identification of essential requirements
- Drawing up project plans
- Prototyping
- Statistical testing
- Stress testing
- Clinical testing
- Osteo-integration testing
- Research on materials, components and packaging
- Chemical cleaning validation (ESCA/SEM/EDX)
- Biological cleaning validation (Bio burden e pyrogenic)
- Biocompatibility validation (Cytotoxicity)
- Sterilization cycle validation
- Packaging validation (accelerated ageing)
- Definitive technical designs
- Definitive plans and control cycles
- Definitive product specifications
- Project validation
- Establishing the definite technical file
- Presentation to the certification body for CE Mark
- CE Mark









PRODUCTION

Nowadays companies tried to offer products and services that not only satisfy but even exceed the customers expectation, reducing, at the same time, their costs to be always competitive.

CAPABILITIES

50 swiss type lathes with bar width from 1 mm to 25 mm

2 Five axis work centres with bar width 42 mm

8 Five axis milling center with automatic loader (Robot)

1 Quality control laboratory with 2D optical scanning machines and 3D mechanical probing machine (DEA)

A company with ISO 9001 and 13485 certification will be able to reach important improvement in terms of organizational efficiency and quality of the product minimizing wastes, avoiding errors and increasing the productivity.

360° SERVICE MEDICAL DEVICE
DESIGN · CAD-CAM · PRODUCTION · FINISHING · CLEANING · VMI SYSTEM

Used materials

Titanium of different grades:

gr.2, gr.3,gr.4, gr.5 ELI F136 and gr.5 ELI F1295

Stainless steel:

303, 304, 316L, 316LVM, 420-A,420B, 430, 630, etc.

Special alloys:

(TZM , NILVAR , Cr Co)

Quenched and tempered steels:

ST 137, ST 329, ET6 88, ET6 100, X 205 Cr12 KU, ecc.

Hardening steels:

18Ni- CrMo5, 16CrNi4, C60, 100Cr6, 39NiCrMo3, ecc.

Alluminium:

(all alloys t4,t5,t6, ERGALL 55, AVIONAL, ANTICORODAL, BT3).

Special plastic:

Delrin, PEEK (DIN 7728 Standard), o and glass reinforced PEEK

PRODUCTION

CAPABILITIES

3 Injection Molding Machinery with clamping force magnitudes up to 45 metric ton.

4 Compression Molding Machinery

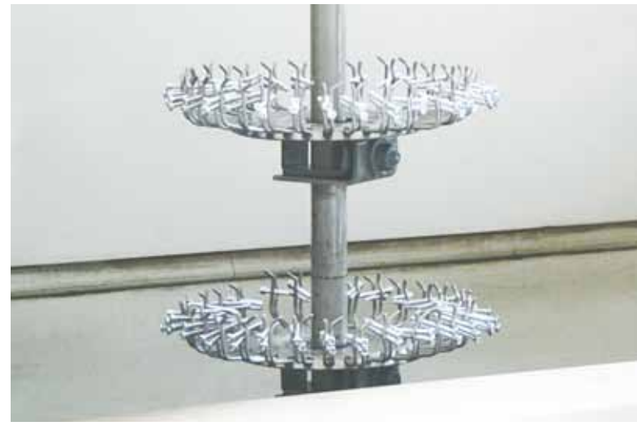
Injection moulding is in area ISO 7; advanced molding technology that allows the production of complex components in large quantity and with limited costs.

All the raw materials used, such polyethylene, CFR Peek, Radel, PLDL, PLLA comply with medical field standards. All products are marked with laser marking, punching, micro milling to allow traceability of the item.

DESIGN
CAD-CAM
PRODUCTION
FINISHING
CLEANING
VMI SYSTEM
360°
SERVICE
MEDICAL DEVICE

FINISHING

- Deburring department
- Shot Peening department
- Sand blasting department
- Tumbling department
- Polishing and elettro-polishing department
- Washing and decontamination department (class ISO 5)
- Titanium elettro-polishing department
- Titanium anodizing process department (class I-II)
- Citric and nitric acid passivation department



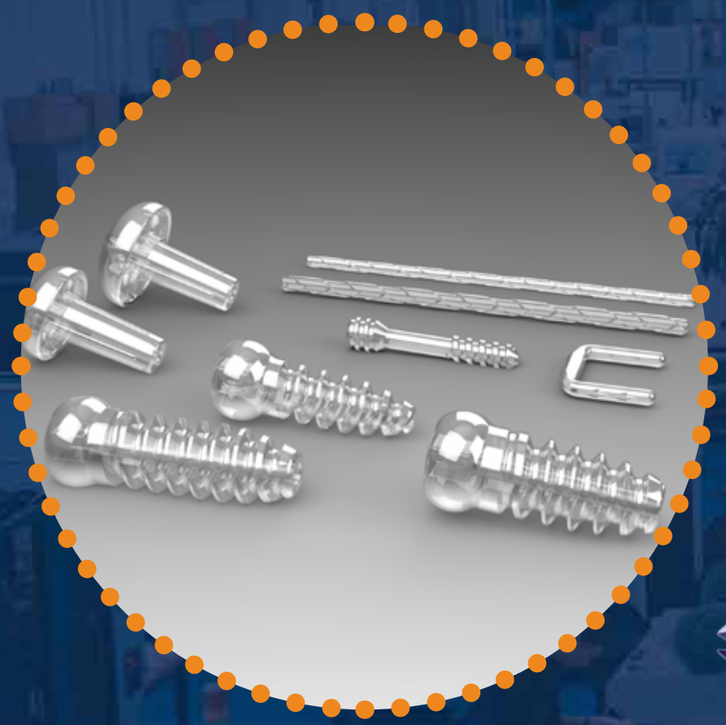
CLEANING
VMI SISTEM

Packaging of the product begins in observance of validated procedures.
For sterile products, the key point in this process is the clean room ISO 7 and ISO 8.
We can handle different type of packaging: blisters, tyvek pouches or vacuum pouches.
The packaging process ends with labelling.

The products are then sent for the sterilization process by external supplier with validated sterilization cycles.

VMI System
Market needs don't very often correspond to the production times of medical devices. To overcome these problems, our company has the so called VMI System (vendor managed inventory) service which allows the control, planning and management of stocks of the customer.

Extremities



Some particular screw, implant o pins can be realized in PLLA resorbable material with injection molding technology.
These products have mechanical properties guaranteed for at least 18 months.

Screws for :

- Hallux Valgus/Osteotomies
- Arthrodesis/Osteosynthesis
- Flat foot correction in child or adult
- Osteotomies and fractures
- Stabilisation - totally intra osseous fixation
- Valgus pronated congenital essential child and adolescent

Self-drilling and self-tapping, cannulated Titanium alloy Ti6Al4V. Progressive conical shape for a better compression
No dorsal impingment.

Spine

Spine:

- Monoaxial and polyaxial pedicle screws
- Hooks
- Straight and angled bars
- Cage (titanium and PEEK)

Trauma

Trauma metallic components

material: Titanium, AISI, CrCo and aluminium

Trauma:

- Nailing system
- LCP locking compression plate & screws
- Screws systems
- Hexternal fixator

Trauma

Trauma polymer components

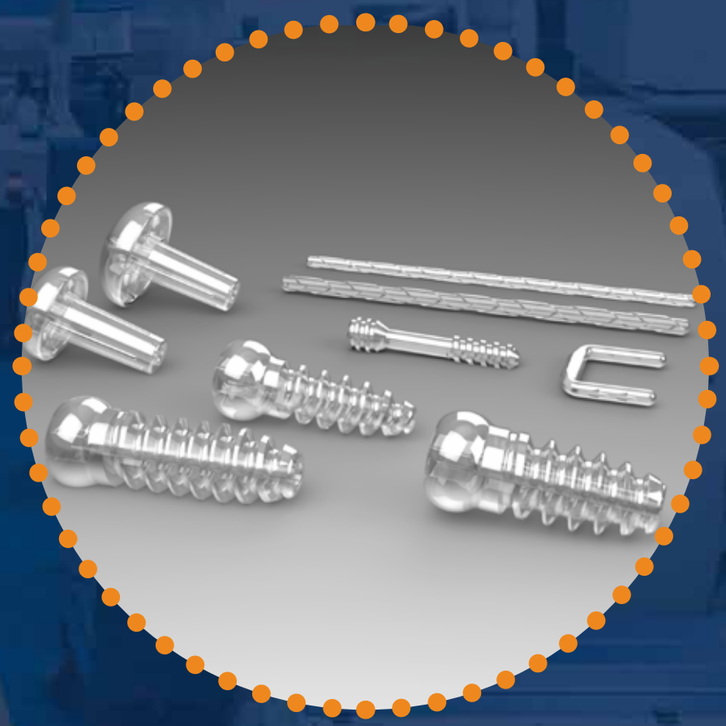
material: peek, CFR peek, PLLA, PDLA

Trauma:

- Plates in CFR Peek
- Screws in PLLA/PDLA*
- Cambre in PLLA/PDLA*
- Pin in PLLA/PDLA*

* Resorbable implants have shown many advantages, for example:

- make bone consolidation easier eliminate the need to remove the synthesis device
- eliminate the visual distortion due to the metal material during the MRI control
- avoid the release of metal ions in bone tissues cage (titanium and PEEK)



Dental

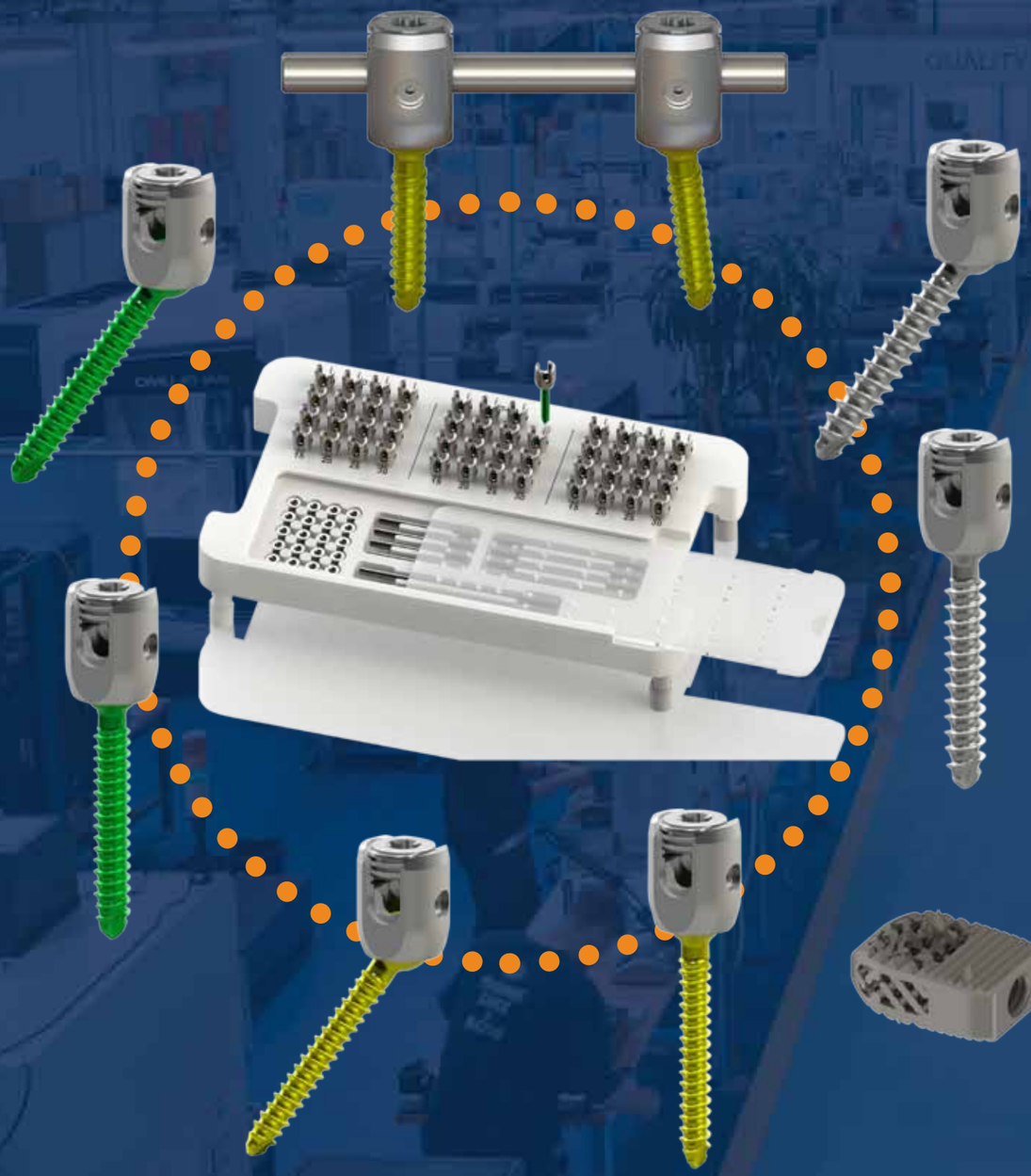
Dental and Maxillo :

- Complete monophasic dental system
- Complete bi-phasic dental system
- Torque ratchet
- Prosthetic components
- Guided surgery
- Cad cam solution

Maxillo

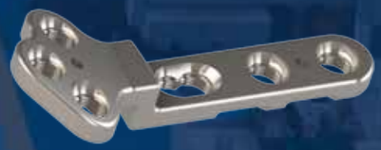
Veterinary

Surgical devices for TPLO procedure & Spine System



EVO

TPLO

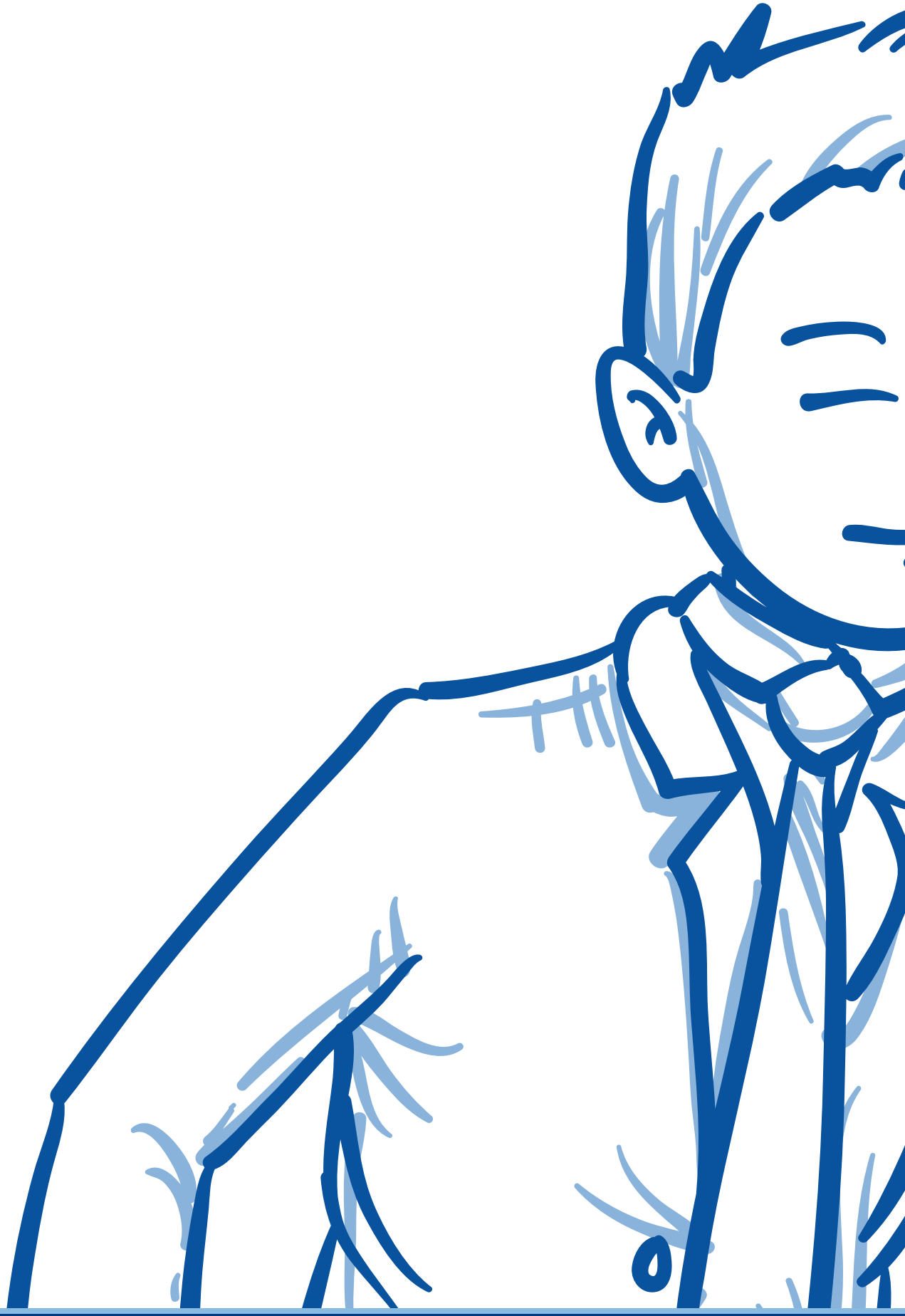


Green lubricant

When we imagine a mechanical workshop, we generally and usually think about dirt. Oil and grease that infest every machine and from which you risk being"dirtied", if you are not careful.
Furthermore, workshops are considered a source of pollution because of the lubricants used for mechanical processing.
This was probably also true in the past and certainly it is the same in some countries where green regulations aren't yet as well implemented as in Western countries!
Anyway, we would like to point out that in our country it is no longer conceivable to work in certain sectors without guaranteeing the respect of sustainability rules.
Even in our company we started being committed in this way many years ago.

Ecology

Nowadays, industrial companies and respect for the environment should match each other.
Leghe Leggere Lavorate fights against pollution thanks to a rational approach regarding the three main mechanics matters: electricity and heat retrieval, waste material disposal and oil treatment.



ONLY 05-2026 LLL EN

ITALY
20090 Buccinasco (MI) Via Lucania, 23/25
Tel + 39 02-45712115 / 3564 r.a.
Fax + 39 02-4880012 r.a.

USA office (Thema corp.)
2929 Arch Street
Philadelphia, PA 19104 – USA
+1-215-8459459 • +1-317-516-8074 (sales)

www.legheleggere.com
sales@legheleggere.com