

BIONEN

medical devices



COMPANY PROFILE

BIONEN S.r.l.

Foundation: 1984, Florence

Sector: Medical Devices

Products: Medical Devices for neurophysiology and other applications.

Certifications: ISO 13485, CE MDR, FDA 21 CFR 820

Address: Florence, Italy

Philosophy: attention to quality and details, internal design and production 100% Made in Italy

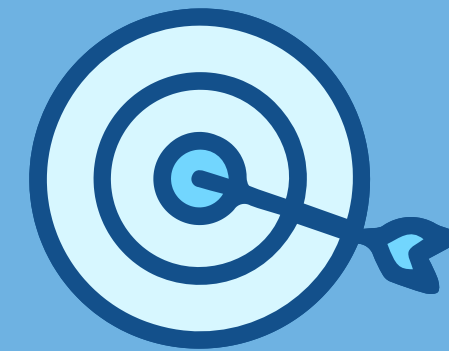
Distribution in over 60 countries around the world

Company structure: family business led by Barbara and Monia Nencioni



VISION

We support Key Opinion Leaders in advancing neurodiagnostics by delivering advanced, reliable solutions that enhance patient quality of life and drive neuroscience research.



MISSION

We are committed to designing, manufacturing, and delivering high-quality neurodiagnostic electrodes and accessories that fulfill the needs of healthcare professionals and researchers in the field of neurology.

Through continuous innovation, manufacturing excellence, and outstanding customer service, we are committed to ensuring accurate diagnoses and effective therapies to improve the well-being of patients with neurological disorders.



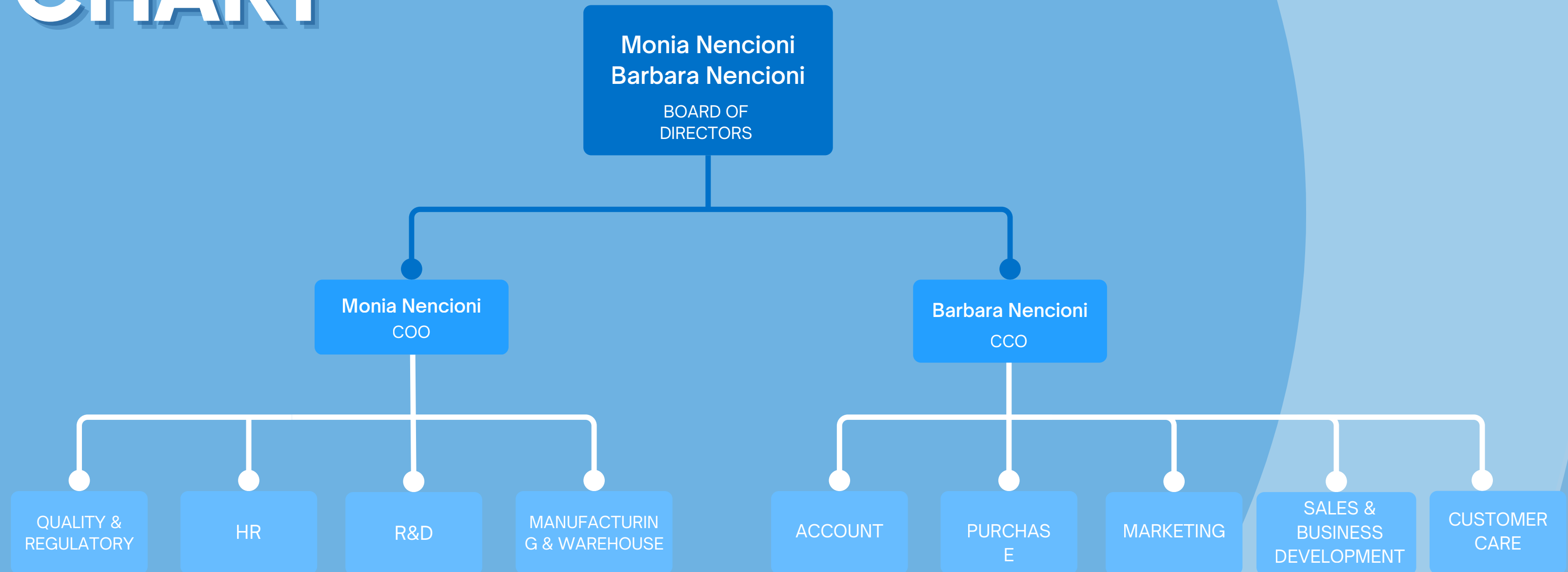
“

Quality is not a detail,
it is the sum of all details.
Our commitment to
sustainability is
transparent, tangible, and
responsible.

”

MONIA NENCIONI
BARBARA NENCIONI

ORGANISATION CHART



SOCIAL RESPONSABILITY



- Safe, inclusive environment; support for parenthood
- 50% women, female representation in leadership roles
- Ongoing training and development

Compliance with Legislative Decree 81/08, proactive prevention, certified personal protective equipment (PPE)



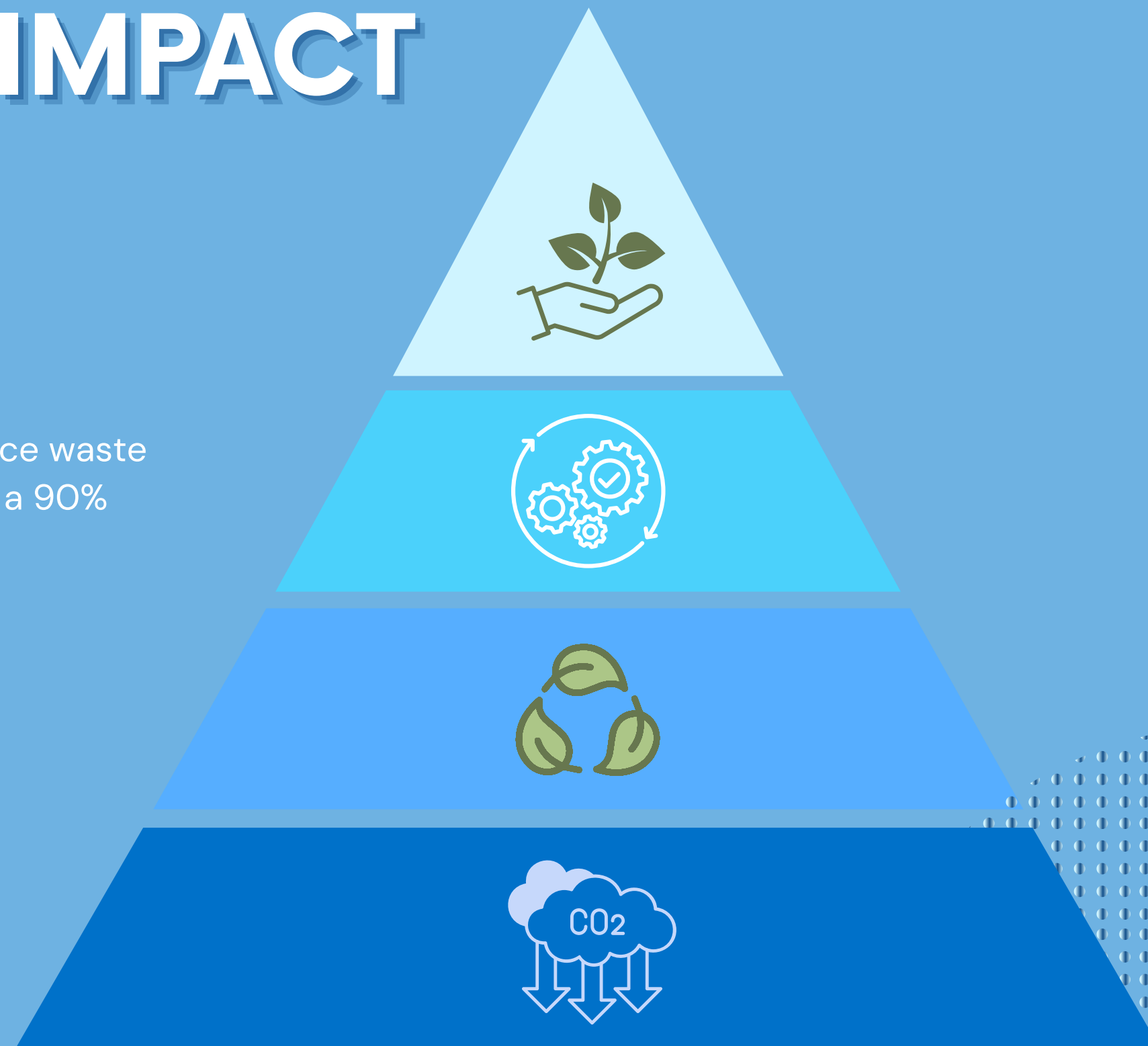
Code of Ethics with zero tolerance for discrimination

Partnerships with universities, hospitals, and research institutions



ENVIRONMENTAL IMPACT

- 01 100% of energy from renewable sources since 2024
- 02 Optimized production processes to reduce waste and digitized documentation, resulting in a 90% reduction in paper usage
- 03 Packaging: –99% plastic, biodegradable materials
- 04 Industrial waste managed by authorized consortia and optimized logistics to reduce CO₂ emissions.



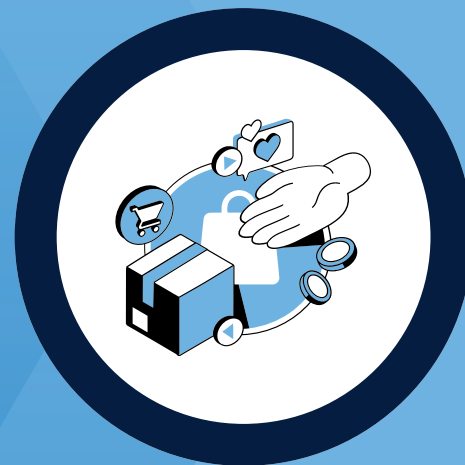
INNOVATION AND PRODUCT

- Design focused on durability, reuse, and waste reduction.
- Introduction of safer materials with fewer residues and improved environmental compatibility.
- Optimized technical packaging: less plastic, more paper, greater efficiency.
- Introduction of QR codes on products for quick guidance and traceability.
- Development of digital interfaces for ordering and technical management.
- Active, multilingual technical support and customer care.



- Ongoing investments in research and development to enhance device functionality, ergonomics, and precision.
- Collaboration with universities, clinics, and key opinion leaders in the neurodiagnostic field.
- Continuous technological upgrades of production machinery.
- Each device undergoes strict quality checks during and after production.
- Certified according to CE (MDR 2017/745), ISO 13485, and compliant with FDA regulations.
- ISO 8 clean-room for contamination control in sterile products.

SUPPLY CHAIN



STRATEGIC PARTNERSHIP

- Long-term collaborations with highly qualified Italian and European suppliers.
- Direct relationships with manufacturers to ensure control over quality, timelines, and traceability.

SELECTION CRITERIA

- Suppliers evaluated based on qualitative, ethical, and environmental criteria.
- Preference given to partners with environmental certifications (ISO 14001), quality certifications (ISO 9001), and REACH/ROHS compliance.
- Periodic audits conducted to ensure adherence to company standards.

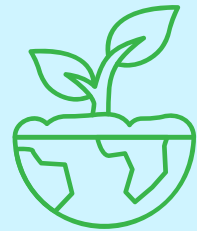
SUSTAINABILITY AND PROXIMITY

- Priority given to local or national suppliers to reduce logistical impact and support the regional economy.
- Reduction of CO₂ emissions related to transportation through optimized planning.

TRACEABILITY AND COMPLIANCE

- Every component is tracked throughout the entire production chain.
- Compliance with EU and international regulations on safety, environment, and materials.
- Use of digital databases for supplier document management.

PERFORMANCE AND KPI



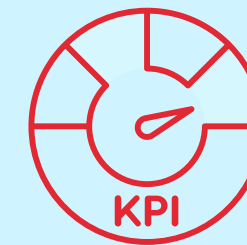
Environmental indicators

- Renewable energy: 100% since 2024
- Plastic reduction in packaging:
 - 99% decrease
- Hazardous waste properly managed: 100%
- Paper consumption: 90% reduction thanks to digitalization



Social indicators

- Number of employees: 24 (12 women, 12 men)
- Female presence in leadership roles: 100%



Product indicators

- Certifications: ISO 13485, CE MDR 2017/745, FDA 21 CFR 820
- Quality checks performed per batch: 100%
- Products returned due to defects: <0.05%



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www.bionen.it

 info@bionen.it

For BIONEN,
sustainability constitutes a
strategic cornerstone rather
than a mere ethical
consideration.

Our development is guided by
a comprehensive integration of
environmental, social, and
technological responsibility.

We are committed to
supporting healthcare
professionals by
upholding the highest
quality standards.
This approach reflects
our commitment to
enhancing the patient
experience and
fostering a more
sustainable and
responsible future.