

	Form		
	Field of application for the integrated HSE management system		
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FIELD OF APPLICATION FOR THE INTEGRATED HSE MANAGEMENT SYSTEM

Excerpt from the Integrated HSE Management System Manual

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The Integrated HSE Management System applies to the following Menarini Group companies:

- **A. Menarini Manufacturing Logistics and Services S.r.l. (AMMLS)**
- **Lusochimica S.p.A.**
- **Lodichem S.r.l.**
- **Menarini Biotech S.r.l. (MBH)**
- **Menarini Ricerche S.p.A. (MR)**
- **Pomezia Engineering & Finance Services S.p.A. (PEFS)**
- **A. Menarini Farmaceutica Internazionale S.r.l. (AMFI)**
- **A. Menarini Industrie Farmaceutiche Riunite S.r.l. (IFR)**
- **A. Menarini Diagnostics S.r.l. (DIAG)**
- **Menarini Silicon Biosystem S.p.A. (MSB)**
- **CODIFI S.r.l.**
- **FIRMA S.p.A.**
- **RELIFE S.r.l.**
- **RELIFE ITALIA S.r.l.**
- **Istituto LusoFarmaco d'Italia S.p.A.**
- **Laboratori Guidotti S.p.A.**
- **Malesci S.p.A.**

The Field of Application for the Integrated HSE Management System takes the following into consideration:

- company activities and their monitoring,
- internal or external factors,
- the expectations and requirements of parties involved,
- the physical boundaries in which all the companies in the Menarini Group operate.

Listed below are the processes to which the Integrated HSE Management System applies, by participating company:

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For Lusochimica S.p.A. e Lodichem S.r.l.:

DEVELOPING AND MANUFACTURING ACTIVE SUBSTANCES FOR THE PHARMACEUTICAL INDUSTRY THROUGH CHEMICAL REACTIONS AND PHYSICAL PROCESSES CARRIED OUT IN SYSTEMS CONSISTING OF REACTORS AND RELATED ACCESSORY SYSTEMS, CENTRIFUGES, FILTERS, DRYERS AND GRANULATORS.

For A. Menarini Manufacturing Logistics and Service S.r.l. and Menarini Biotech S.r.l.:

MANUFACTURING MEDICINES, PHARMACEUTICAL PREPARATIONS AND BIOTECHNOLOGICAL PRODUCTS ACROSS THE STAGES OF STORAGE AND MANAGING RAW MATERIALS, FORMULATION, PACKAGING AND SHIPPING.

For A. Menarini Manufacturing Logistics and Service S.r.l. e A. Menarini Farmaceutica Internazionale S.r.l.

LOGISTIC ACTIVITIES TO SUPPORT THE MARKETING OF MEDICINAL PRODUCTS AND PHARMACEUTICAL PREPARATIONS.

For Menarini Biotech S.r.l. and Menarini Ricerche S.p.A.:

SCIENTIFIC AND TECHNOLOGICAL RESEARCH IN THE BIOTECHNOLOGY, PHARMACOLOGY AND TOXICOLOGY SECTORS THROUGH LABORATORY TESTS AND OTHER REGULATORY ACTIVITIES.

For A. Menarini Farmaceutica Internazionale S.r.l., A. Menarini Industrie Farmaceutiche Riunite S.r.l., A. Menarini Diagnostics S.r.l., Menarini Silicon Biosystem S.p.A., CODIFI S.r.l., FIRMA S.p.A., Istituto Lusofarmaco d'Italia S.p.A., Laboratori Guidotti S.p.A. and Malesci S.p.A.:

MARKETING MEDICINAL PRODUCTS, PHARMACEUTICAL PRODUCTS, PRODUCTS OBTAINED THROUGH MOLECULAR BIOLOGY, PARAPHARMACEUTICAL GOODS, DIAGNOSTICS DEVICES (AND RELATED EQUIPMENT, INCLUDING DEVELOPMENT), ELECTROMEDICAL AND BIOTECHNOLOGICAL DEVICES (AND RELATED EQUIPMENT, INCLUDING DESIGN, DEVELOPMENT AND RELATED DATA PROCESSING PROGRAMS), COSMETICS, DIETARY PRODUCTS, HEALTHCARE AND SIMILAR PRODUCTS, IN ITALY AND ABROAD.

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For Relife S.r.l. and Relife Italia S.r.l.:

RESEARCHING, DEVELOPING, MANUFACTURING, PURCHASING, SELLING, IMPORTING, EXPORTING, STORING AND TRADING IN PHARMACEUTICAL, DIETARY, COSMETIC AND PERSONAL HYGIENE PRODUCTS IN GENERAL, MEDICINAL PRODUCTS, MEDICAL DEVICES, ELECTRONIC EQUIPMENT AND SURGICAL OR OTHER INSTRUMENTS WHICH HAVE THEIR OWN USE IN THE PHARMACEUTICAL, MEDICAL, COSMETIC AND PERSONAL HYGIENE FIELDS, THE TECHNOLOGIES, THE KNOW-HOW RELATED TO THE ABOVE-MENTIONED PRODUCTS, AS WELL AS THE PROVISION OF SERVICES.

For A. Menarini Diagnostics S.r.l.:

MARKETING, DISTRIBUTION AND SUPPORT FOR IN-VITRO DIAGNOSTICS SYSTEMS AND DEVICES, ACCESSORY MEDICAL DEVICES FOR SELF-MONITORING AND BLOOD GLUCOSE MONITORING.

For Pomezia Engineering & Financial Services S.p.A.:

PROVIDING COLLATERAL AND SUPPORT SERVICES MAINLY FOR THE BENEFIT OF MENARINI GROUP COMPANIES (OPERATING IN THE CHEMICAL PHARMACEUTICAL SECTOR) WHICH ARE TECHNICAL AND ENGINEERING IN NATURE, AS WELL AS FACILITY MANAGEMENT, PLANNING SUPPORT SERVICES MAINLY FOR MENARINI GROUP COMPANIES, INCLUDING PROVIDING SERVICES AND THEREFORE ALSO OPERATIONAL MANAGEMENT, PLANNING AND MANAGING ICT SYSTEMS AND SERVICES, HEALTH, SAFETY AND ENVIRONMENTAL CONSULTING IN COMPLIANCE WITH CURRENT NATIONAL REGULATIONS AND DEVELOPING MANAGEMENT, ENVIRONMENTAL AND SECURITY SYSTEMS TO OBTAIN VOLUNTARY CERTIFICATION, MANAGING ADMINISTRATIVE SERVICES, MANAGEMENT CONTROL, PURCHASING AND HUMAN RESOURCES.

For Menarini Silicon Biosystem S.p.A.:

DESIGN, DEVELOPMENT, MANAGEMENT OF MANUFACTURING AND TRADE OF ELECTRONIC, MECHANICAL, CHEMICAL, MEDICAL AND ELECTROMEDICAL SYSTEMS, AS WELL AS DATA PROCESSING PROGRAMS, WITH REGARD TO THE SAME SECTORS. PROVISION OF CHEMICAL AND BIOLOGICAL ANALYSIS, RESEARCH AND DEVELOPMENT SERVICES IN THE BIOTECHNOLOGICAL FIELD.

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Third parties also carry out these activities, and they, appointed by the Menarini Group, provide services that are necessary to business activities. Menarini Group companies have the potential to influence these third parties in aspects regarding the environment and health and safety at work (e.g. evaluation of interference risks) connected to the various plants on the basis of contractual relationships for supplying goods and services.

Third parties may be outsourcers for materials and products or *service contractors* that provide services in the plants. The main services provided may concern:

- checking and maintaining emergency management tools (fire prevention and first aid),
- security and access control,
- health monitoring and infirmary,
- waste collection for recovery or final disposal and transport,
- company canteen,
- cleaning,
- maintaining systems, equipment and buildings,
- HSE monitoring and evaluation,
- chemical, physical and biological analyses and specific aspects regarding safety and the environment.

The Management System considers all the management processes of third parties (*outsourcers and contractors*) in the assignment of the supply of materials and products and the procurement of services, taking into account the interrelationships of these processes with company departments — from the qualification phase to the definition of technical specifications during the tender phase, from the identification of environmental aspects and the health and safety requirements that must be complied with during execution to the presence of professional qualifications, from the definition of the contract to the monitoring and evaluation of implementation methods in the field.

With the goal of preventing risks and developing opportunities with regard to the environment and health and safety at work, the Integrated HSE Management System is also applied to the processes for defining corporate investments.

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The field of application for the HSE System is therefore represented by the activities and operations described above and is made available as documented information to the parties concerned through the institutional Internet portal: www.menarini.com.

In determining the field of application for the HSE Management System, Menarini Group Management carried out an analysis and assessment of the company context, thanks to which all the internal and external factors attributable to the parties concerned that may affect the achievement of the environmental management and health and safety objectives or the conditions that can influence the business development of the Menarini Group and its products and services on the market were identified.

The expectations of the parties concerned that are identified and assessed in the fields of the environment and safety at work (internal/external) contribute to determining company risks and opportunities and to assessing priorities for the consequent adoption of risk mitigation measures or actions to create opportunities.

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