innofamily since 70's

INDEX

HAEMOPHARM HEALTHCARE

Unique in its field

Haemopharm Healthcare manufactures flexible IV bags (PVC / PVC free, single / multi-chamber), drug reconstitution and delivery systems, closed system transfer devices (CSTD) Ready-to-Use and Ready-to-Transfer for various pharmaceutical and medical applications.

Founded in the 1970s on the basis of the family enterprise Gobbi Frattini, a pioneer in the field of automated manufacturing of medical devices, Haemopharm Healthcare has achieved a leading role in the international market, qualifying itself as a leader in the infusion sector.

Haemopharm is distinguished by a very high level of specialization, a constant commitment to Research & Development of innovative products, with a particular focus on the development of advanced systems and components for drug reconstitution and delivery to a patient, designed and produced entirely inhouse. Many of them are patented and have unique characteristics on the market.

One of the important competitive advantages of Haemopharm is the exclusive and patented machines for production of sterile bags and moulds, which has been the flagship of the company from the very beginning.

Over the years, Haemopharm has always remained true to its values and identity, rooted in the history of the company, ever since its founder Mr. Renzo Gobbi Frattini played a pioneering role in the automated production of flexible bags for the biomedical sector.

Today, Mr. Paolo Gobbi Frattini, the 2nd generation CEO, owns 100% of the share capital and is present and active in the Group, guaranteeing sustainable long-term growth and development. This is one of key aspects of company's uniqueness, it facilitates communication, speeds up the decision-making process and allows us to satisfy the most sophisticated requirements of our customers.

From Industrial Research to Medical Treatment. Haemopharm is a unique entrepreneurial structure with own clinical division, the St. Agatha Medical Center, which represents company's DNA and its natural tendency to work closely with the medical-scientific world.

STRATEGIC GUIDELINES

Haemopharm's mission is to consolidate its technological leadership by developing numerous patents and grow steadily as the partner of choice for large international companies.

Its international expansion strategy is embedded in a broader growth logic focused on building a modern and dynamic organization capable of competing globally and being the first to enter specialized markets with high quality products.

The dynamic entrepreneurial spirit, constantly focused on striving for excellence over a history of more than 30 years, places three fundamental strategic assets at the center of the company's life, which represent the Pillars of Haemopharm Vision:

Innovation. In PROCESSES, thanks to the proprietary technology of automated production machines and to the modular and versatile production management; in PRODUCTS, as Haemopharm develops devices with advanced functionality and high added value; in COMPETENCES of the Haemopharm's Team, with the highest professional qualifications and many years of continuous experience with an advanced design approach.

Diversification. Haemopharm's solutions meet the needs of various therapeutic areas, such as pharmaceutical compounding, drug reconstitution, dialysis, nutrition, cryopreservation of cells and tissues, ozone therapy, ophthalmology, odontology – and the list goes on.

Partnership. With a consolidated network of partnerships and collaborations, Haemopharm is able to fully use its strategic potential throughout the supply chain and manage every single phase of a project with the highest quality and efficiency, in the shortest time frame.

MILESTONES

1960 The Family Company starts its activity as a forerunner in the automated production of medical devices.

1978 Foundation of an Individual Company Paolo Giuseppe Gobbi Frattini.

1985 Production site licensing authorization for Medical and Surgical devices defined as “Plastic infusion sets for infusion and dialysis solutions”, N. 800.5.OFF.820.3704.

1986 Opening of a commercial office in Milan.
Ministry of Health Registration No.15.828 of COMBYSet 2G medical and surgical unit for infusion and dialysis solutions.

1988 Production site licensing authorization for Medical and Surgical devices defined as “Containers for tubular devices in plastic for infusion solutions, dialysis, blood and its derivatives”, No.800.5.OFF.820.2525.

1989 Ministry of Health Registration No. 14.928 of the Medical-Surgical empty bag system AUTOBag for infusion and dialysis solutions.

1993 Ministry of Health licensing No. 35243 for the commercialization of infusion and dialysis solutions listed in the national galenic form.
Ministry of Health licensing for the commercialization of the cumulative package 001 AC PRIMINGLine Na-Cl 0.9% solution in double bags for priming in haemodialysis and COMBYSet 2G infusion set.

1995 Ministry of Health maket authorization for infusion and dialysis solutions packaging in bags, glass bottles and vials.

1996 Foundation of the company Haemopharm Healthcare s.r.l.

1997 Extension (900.2 / 16.SO.7.3934) of the Ministry of Health Registration No. 14.928 of the medical-surgical empty bag system Autobag for drug reconstitution, called SHARPbag.
Extension (900.2/16.SO.7.3934) of the Ministry of Health registration N. 14.928 of the Medical- Surgical empty bag system Autobag for peritoneal dialysis system, called PERILine.
Ministry of Health Registration No. 14.928 of the Surgical Medical Presidium empty bag system NUTRILine infusion set and bags for parenteral/enteral nutrition.

1998 UNI EN ISO 9002 certification n. 9120 PGBF.
UNI CEI EN 46002 certification n. 9124 PGB2.
ISO 9002 certification n. IT1592.

1999 Inauguration of the new production facility in Tovo di S.Agata (province of Sondrio).

2002 Establishment of the Biofluids Division, specialized in drug manufacturing and bag filling.

2003 ISO 9001: 2000 certification n. 9120 PGBF.
EN 46002 ISO 13485: 1996 certification n. 9124 PGB2.

2006 Market Authorization for hemofiltration solutions in Austria Nos. 1-26257, 1-26258, 1-26259 and 1-26260.
UNI EN ISO 9001: 2000 certification cert. n. 5783-A.
UNI EN ISO 13485: 2004 certification, cert. n. 5783-M.

2010 Registration at the Colombian Ministry of Health N. 2010DM-0005986 of the medical device NUTRILine, infusion set and bags for parenteral / enteral nutrition.

2011 Foundation of the pharmaceutical company Quatalia Science d.o.o. in Belgrade, Serbia.
Registration at the Russian Ministry of Health N. FSZ 2011/10243 of the medical device Polyolefin, bags for filling and storage of infusion solutions, with components.

2012 Registration N.30061090 at the Ministry of Health in Venezuela of the medical device NUTRILine infusion set and bags for parenteral / enteral nutrition.
UNI EN ISO 9001: 2008 certification n.5783-A.
UNI EN ISO 13485: 2012 certification n.5783-M.
Opening of the clinical division - Medical Center St. Agatha S.r.l.

2012 GOLD WINNER at the CPhI Pharma Awards “Best Innovation 2012” for the NIV® product: “Needle-free Vial closure system”.

2013 DMF n. 27342, Type III, submitted at FDA for “Plastic bags for Pharmaceutical Solutions and Their Components”.

2014 FINALIST at CPhI Pharma Awards in the category “Packaging” for the product FILLChoice® room: a new concept of a compounding pharmacy in a bag (CSTD Ready-to-Use).

2015 ADVATIS: establishment of the JV between SIAD Healthcare (now Medigas Italia Srl) and Haemopharm Healthcare. The companies started cooperating by developing the SAFE2® product line of innovative and customized solutions in cell therapy.
Starting from 1 July 2015, the Individual Company Paolo Gobbi Frattini became Paolo Gobbi Frattini S.r.l. (sole shareholder).
The PAOLO GOBBI FRATTINI group expands into the new production areas. The company opens a fully operational compounding department for aseptic production of sterile fluids.
The St. Agatha Medical Center significantly expands its range of therapies.

2016 Creation of the iDone brand, a line of products dedicated to Ophthalmology.
Establishment of the company Lu Scientific d.o.o. in Belgrade, Serbia.

2017 Creation of the Alimenta brand, a new line of bags for parenteral nutrition, produced with an innovative material that increases the quality of TPN bags.

2019 ANVISA Regulatory Authorization n. 8047823 at the Brasilian Ministry of Health for Class III medical devices

2021 FINALIST at Tech beauty contest promoted by Digital Hub Lombardia (Confindustria) for the category Digital Process Innovation for its proprietary online in-line parametric and integrated AI cam quality control.
FINALIST at CPhI Pharma Awards in the category “Best Innovation: Packaging & Drug delivery” with the product FillChoice® Refill, a closed-system for multivial drug reconstitution and administration (CSTD Ready-to-Transfer).

2022 FINALIST at CPhI Pharma Awards in the category “Best Innovation: Packaging & Drug delivery” with the product FillChoice® Lung, a closed-system drug reconstitution and transfer device with pressure equalisation (CSTD Ready-to-Transfer).

RESEARCH & DEVELOPMENT

Opinion leaders in Medical Science have always been a point of reference for Haemopharm. The company devotes significant resources to fund research & development, mainly aimed at the design of delivery systems with advanced functions, complex biomedical devices for storage and manipulation of various types of pharmaceuticals, as well as sensitive biologicals, such as cells, tissues, organs. Our R&D mainly lays in the three areas:

New products. Development begins with an in-depth study of the therapeutic needs of users they are intended for, with the aim to offer innovative solutions to the most common problems and discover new applications.

Innovative and high performance materials. Our company offers state-of-the-art materials of the highest quality (in terms of container-content compatibility, barrier properties, etc.), suitable for the production of bags and components for pharmaceutical and medical sectors, finding or creating the most suitable requisites for each specific project, to ensure the best safety and stability of a drug.

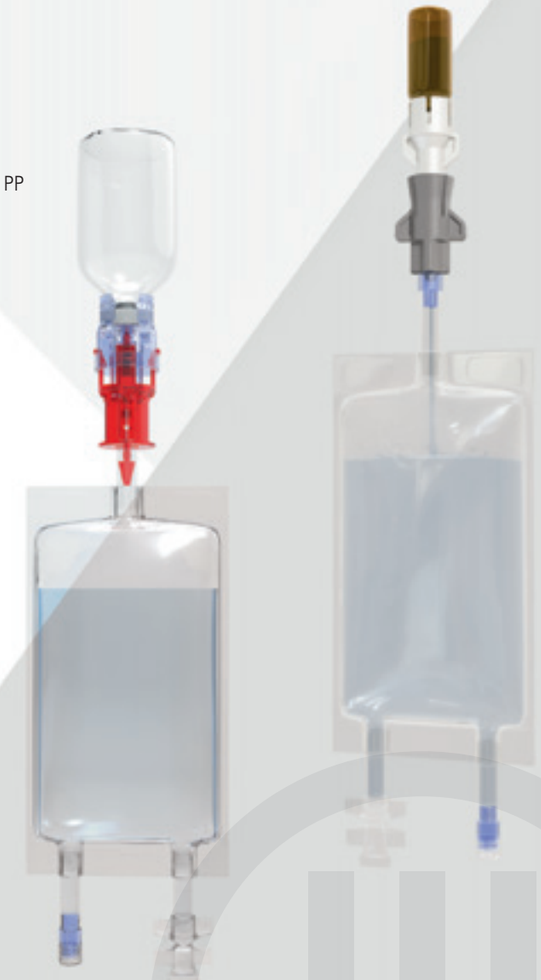
New automated machinery. Haemopharm's name stands for the proprietary technology and its own inhouse design and manufacturing of moulds and new automated machines for PVC and PVC-free bags. The outstanding engineering, specialised know-how and a large well-equipped in-house workshop enable Haemopharm to manage the entire production cycle, from custom machinery construction and mould making to prototyping and finished product manufacturing.

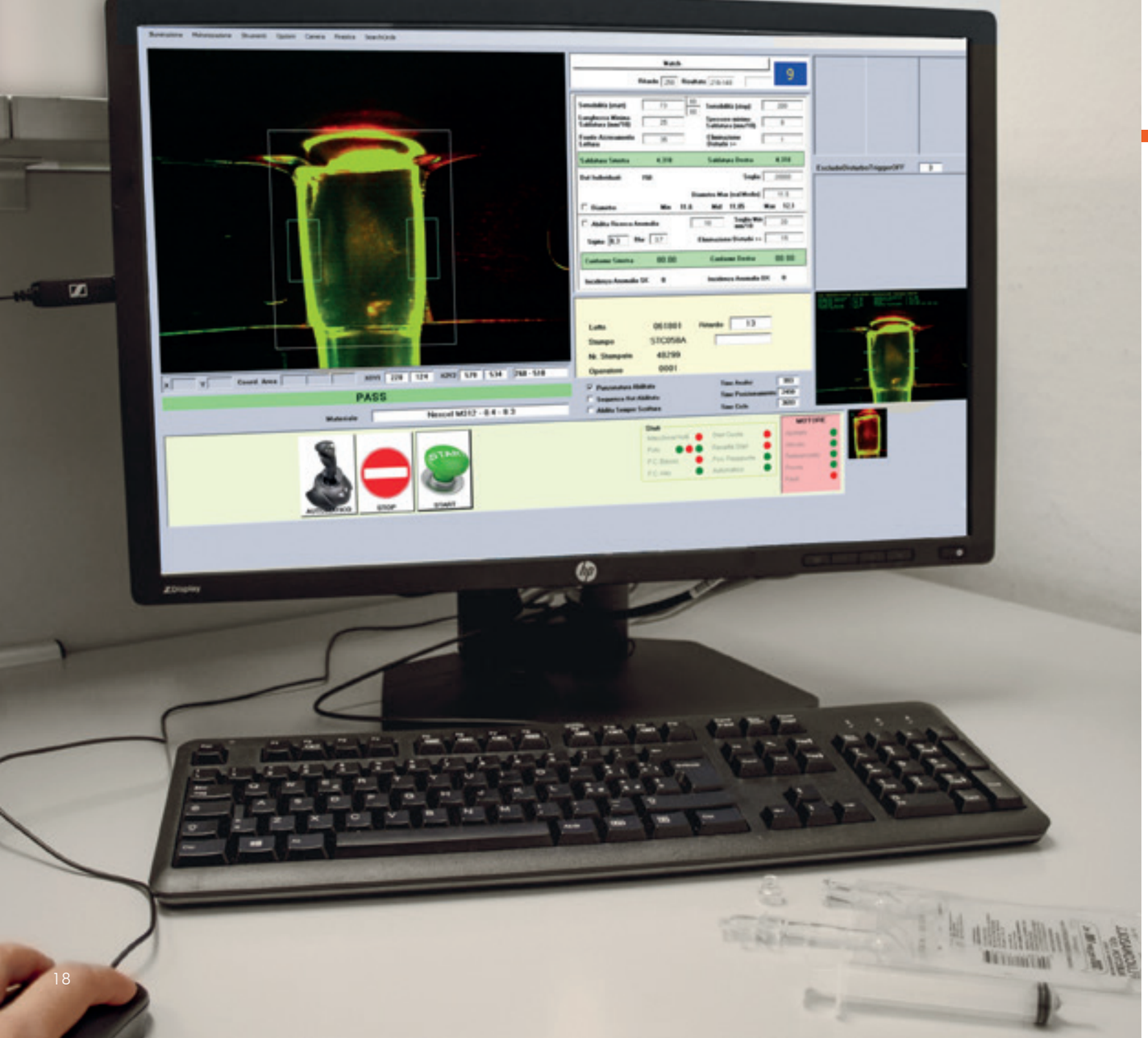
PRODUCTS

FLEXIBLE BAGS
PVC / PVC DEHP Free / PVC Free – EVA, PP
Single / Multi-Layer
Single / Multi-Chamber

COMPONENTS
Needle-free Connectors
Needle-free Stoppers
Breakable Connectors
Infusion Sets
Extension Sets

FINISHED PRODUCTS FOR MANY THERAPEUTIC AREAS
IV Administration
Drug Reconstitution
Oncology
Urology
Ophthalmology
Ozone Therapy
TPN dialysis
Clinical Nutrition
Blood and Cell Therapy
Wound Care





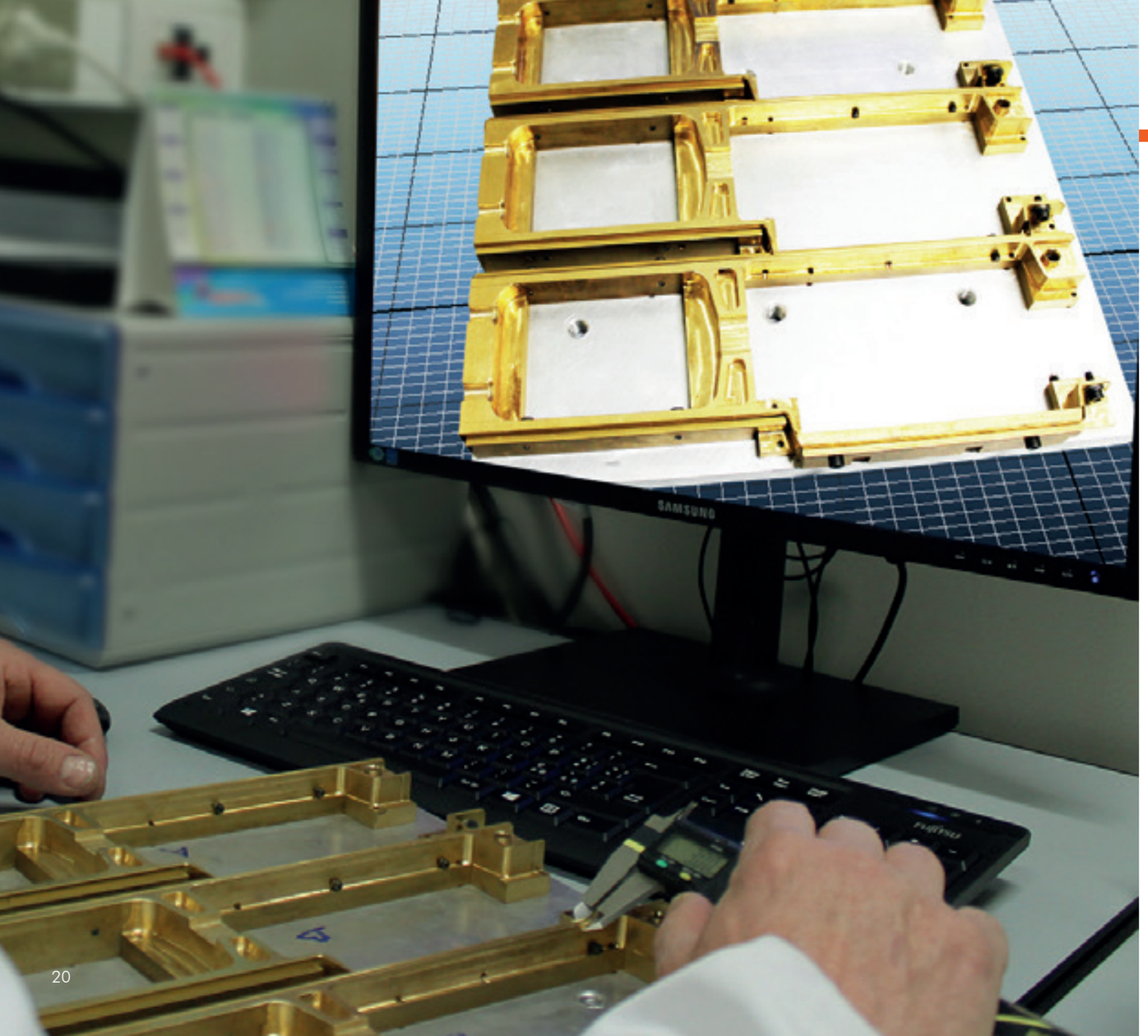
PRODUCTION & QUALITY CONTROL

All Haemopharm products are CE marked, as safety is the core value for the company. Moreover, every day the company devotes its full attention to the efficiency and quality of the production processes. Parameters of each plant are constantly monitored using proprietary software and a state-of-the-art vision system.

The quality system is certified and compliant with ISO 9001:2015 and ISO 13485:2016 standards for the production, design and marketing of wide range of disposable medical devices for infusion, nutrition, transfusion, cryopreservation and more.

All the production and analysis phases take place in a Clean Room, in a controlled contamination environment and in compliance with the UNI EN ISO 14644-1,2,3, UNI EN ISO 14698-1,2, UNI EN ISO 17141: 2021 and Annex 1 standards GMP.

Artificial Intelligence based monitoring system. Haemopharm has implemented an innovative AI-driven online parametric control system with cameras embedded along the production line, allowing the 100% product inspection. It operates on the basis of a proprietary software designed specially to recognise all production steps, and it guarantees a top-level quality for the products.



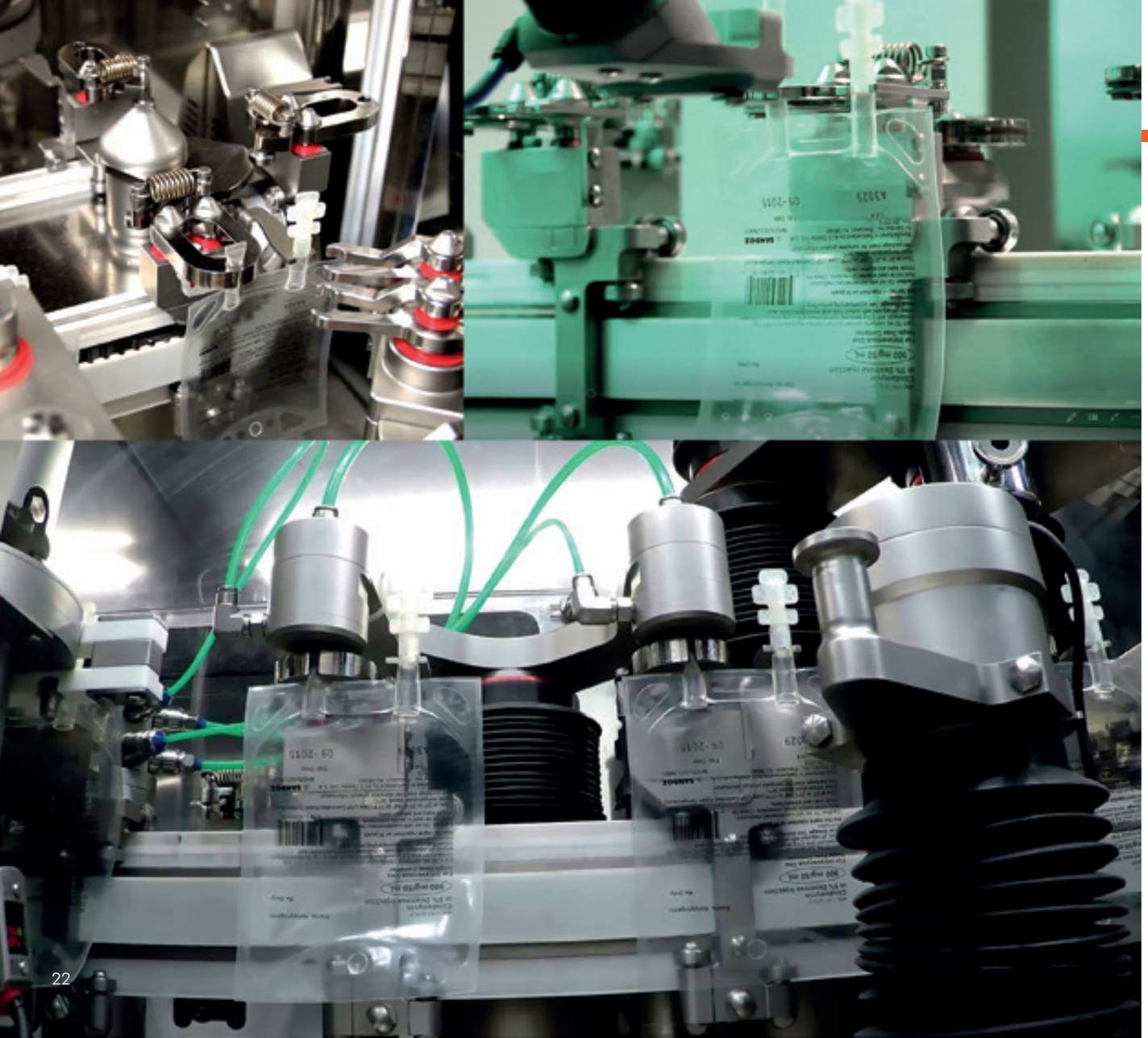
IN
CONTRACT MANUFACTURING

From Feasibility to Design & Manufacture. Bringing your ideas to life, we conduct an in-depth analysis of therapeutic needs and intended use, resulting in an optimal product requirement.

Thanks to the company's life-long know-how and its highly professional team, Haemopharm finds the best solutions for specific applications, assuring the support to the companies in the medical and pharmaceutical sector with sufficient organizational structure and production capacity, that allow Haemopharm to carry out complex R&D projects.

Standard vs. Tailor-made. In response to specific needs, Haemopharm is capable to design and deliver a tailor-made product, with the advantage of Just-in-time (JIT) manufacturing. Carefully managing every production step as a Single Supplier, including manufacturing of customized moulds and automated machines, up to the sterilization validation of a finished product, Haemopharm delivers semi-finished or finished products compliant to the most rigid quality requirements of our clients.

On the top of that, the company offers to the market a unique level of business and production flexibility, guaranteeing excellent quality in the shortest possible time and at a competitive price.



OUT
CONTRACT MANUFACTURING

Aseptic filling of IV Bags is one of the core activities of Haemopharm for pharmaceutical and biotech industry.

Haemopharm maintains a set of strategic partnerships with global pharmaceutical companies (FDA approved) that have filled empty bags produced by Haemopharm with various types of sterile solutions over the years.

A dedicated division manages and controls pharma outsourcing, so that our customers can count on:

- Excellent quality
- High customization
- Local Marketing Authorizations for finished products
- Thoughtful selection of the most appropriate packaging characteristics (small/large volumes, single/multi-chamber design, top-quality materials, proprietary connectors, sealings and more)
- Reduced production costs
- Lower logistic and transport costs

TRADEMARKS

1993 UROPOKET™ Registration n. 00685903

PRIMINGLINE™ Registration n. 674438

1995 PERILINE™ Registration n. MI95C 007726

1996 SHARPBAG™ Registration n. M216C 009280

2003 HAEMOPHARM™ Registration n. 003460805

2010 FILLCHOICE™ Registration EU n. 009099615

FILLCHOICE™ Registration USA n. 3977292

2011 TISSUECHOICE™ Registration EU n. 010123602 by Paolo Gobbi Frattini and Medigas Italia S.R.L.

STEMCHOICE™ Registration EU n. 010123644 by Paolo Gobbi Frattini and Medigas Italia S.R.L.

NIP™ Registration USA EU n. 010485118 and USA n.4267010

2012 NIV™ Registration USA EU n. 010957587 and USA n. 4500243

2013 INFUSIONCOLOGY™ Registration n. 012399358

2014 SAFE2™ Registration EU n. 1205983 and USA n. 4639158

2015 ADVATIS™ Registration n. MI2015C000167 by Paolo Gobbi Frattini and Medigas Italia S.R.L.

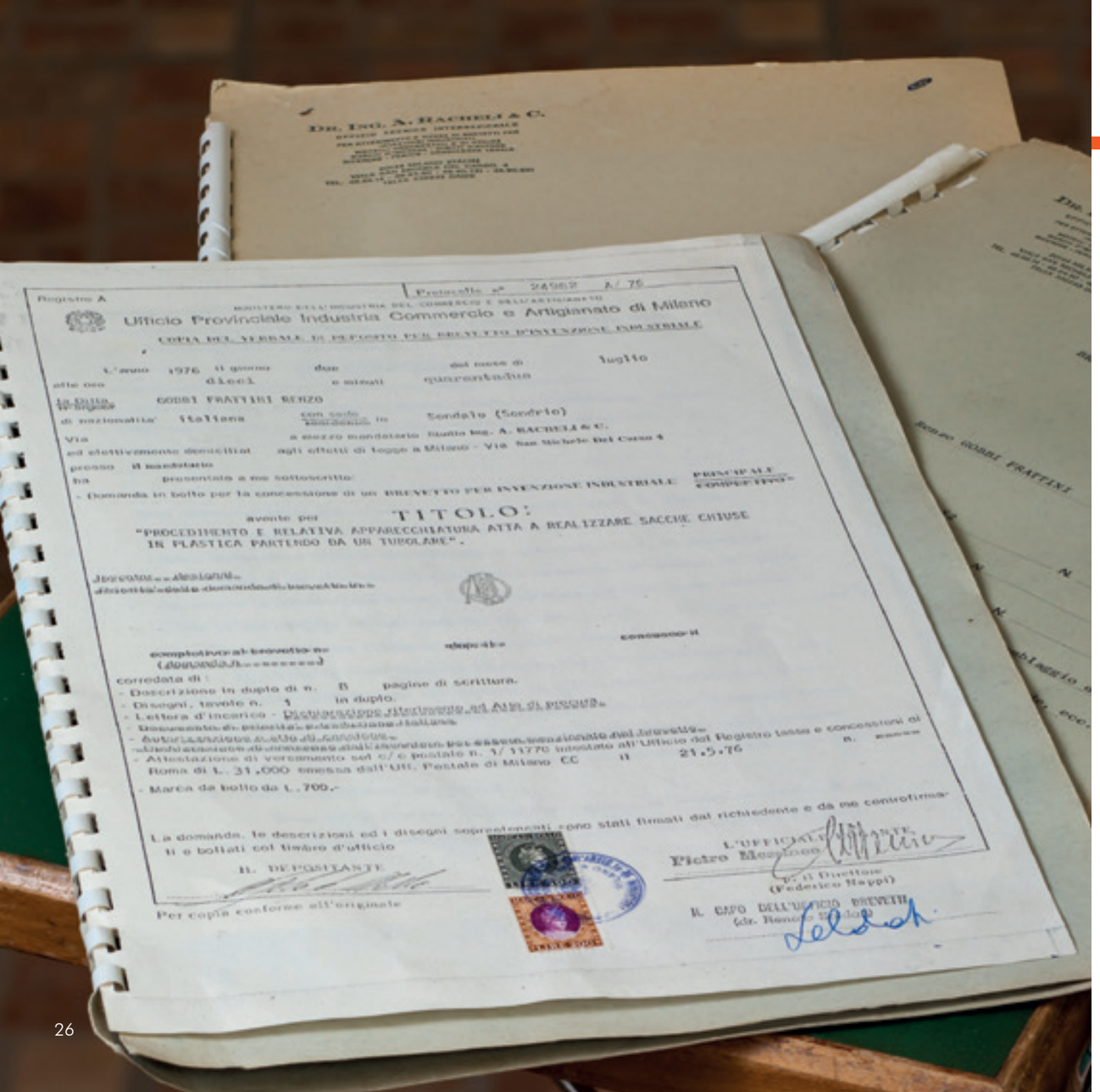
ADIPOCHOICE™ Registration EU n. 013922208 and USA n. 4888307 by Haemopharm and Medigas Italia S.R.L.

CORDCHOICE™ Registration EU n. 013922174 and USA n. 4888306 by Haemopharm and Medigas Italia S.R.L.

2020 FILLCHOICE™ International Registration IR n. 1543440 by Paolo Gobbi Frattini and ADIENNE Pharma & Biotech SA

FILLCHOICE™ Registration HONG-KONG n. 305312934 by Paolo Gobbi Frattini and ADIENNE Pharma & Biotech SA

FILLCHOICE™ Registration TAIWAN n. 02137734 by Paolo Gobbi Frattini and ADIENNE Pharma & Biotech SA



PATENTS

DEVELOPED BY RENZO GOBBI FRATTINI

1976 Automatic machine for the manufacturing of medical empty bags

1982 Automatic machine for the manufacturing of infusion sets

1984 Intravenous flow regulation system

1991 Machine for the automatic production and packing of infusion sets (registered under the name Paolo Gobbi Frattini)

DEVELOPED BY PAOLO GOBBI FRATTINI

1995 PERIGLASS, sterile environment connection device for CAPD catheter

1996 SHARPBAG®, bag for drug reconstitution

1999 Connection device for CAPD catheter

2003 HFLINE Double bag for hemofiltration

2007 SANO3 Kit for oxygen-ozone therapy and its method of use

2008 WASHOUT Device for wound washing

2010 FILLCHOICE® DOSE Bag for dosed drug reconstitution

2011 NIP® Needlefree connector / BREATHCHOICE Double bag for lactose intolerance breath test

2012 FILLCHOICE® SMART Three-way bag for drug reconstitution / NIV® Needlefree Vial Stopper

2013 "Bag for liquids" / "Method for treating blood cells before separation"

2014 FILLCHOICE® ROOM System for drug reconstitution / "Method for treating blood cells before separation"

2015 ADIPOCHOICE® SMART System for adipose tissue treatment / FILLCHOICE® ROOM, and its sterilization method

2016 FILLCHOICE® ROOM DOSE System for dosed drug reconstitution / SIV® System for sterile connection

2018 NIP MALE, male needle free connector

2019 i-Safer, Sterile drop dispenser for multiple use
FILLCHOICE® two-ways connector for drug reconstitution.

2020 Luer Vial adapter
Twist.off ZERO, Spike port with interlocking fastening system

2021 REFILL® System, Vial connector for multi-vial drug reconstitution systems
"Bag for containment and irrigation of a solution for washing and disinfection of dental surgical field".
FILLCHOICE® LUNG, CSTD with pressure equalisation for drug reconstitution and administration.

CE MARKS, FDA DMF & OTHERS M.A.

2004 CE MARK of "NUTRILINE, sterile bag for parenteral and enteral nutrition".

2005 CE MARK of "PERILINE®, patient set for peritoneal dialysis" / "COMBYLINE, HAEMOLINE, FLOWLINE, UROLINE, medical devices for infusion and transfusion, sterile" / "UROFLUSH, solution G and UROFLUSH solution R"/"SAFE2®, bags for cryopreservation of stem cells"/"SAFE2® STEMCHOICE®, bag for cryopreservation of stem cells, sterile" /"SAFE2® TISSUECHOICE®, bag for cryopreservation of tissues, sterile" / "FILLCHOICE®, bag with sterile solutions for washing, irrigation and instillation" /"Sterile and non-pyrogenic solutions for washing and irrigation" / "Solutions for continuous renal replacement therapy, sterile".

2007 CE MARK of "WASHOUT, bag with sterile solutions for washing and irrigation" / "CITRACHOICE, sterile solution for CRRT" / "MIXSOL, sterile solution for continuous renal replacement therapies".

2008 CE MARK of "SANO3, set for auto haemo-infusion with ozone, sterile".

2009 CE MARK of "Solutions for continuous replacement dialysis therapies" / "Disposable for APD, sterile" / "Collection bags, sterile"

2010 COLOMBIAN REGISTRATION INVIMA of "NUTRILINE, sterile bag for parenteral and enteral nutrition".

2011 RUSSIAN REGISTRATION of "Polyolefin bags, injection point, vial stopper".

2013 FDA Device Master File n.27342 of "Plastic bags for pharmaceutical solutions and their components" for Class III.

2014 CE MARK of "INFUSIONCOLOGY®, infusion sets designed specifically for oncology".

2015 CE MARK of "Liquid for the preservation of corneal graft in hypothermic conditions up to 14 days, sterile: iRESTORE Conservation, sterile".

2017 CE MARK of "ADIPOCHOICE®, bags for cryopreservation of tissues, sterile".

2019 CE MARK of "ALIMENTA, Sterile bags for Total parenteral Nutrition TPN in polyolefin material".

2020 CE MARK of "Liquid for the preservation of corneal graft up to 30 days, sterile: iRESTORE Culture" / "Liquid for the deturgescence and transport of the corneal graft at room temperature up to 5 days, sterile: iRESTORE Transport".

A GLOBAL BUSINESS NETWORK

Pharmaceutical and Biotech companies are increasingly sensitive to establishing new business relationships, and choose more often suppliers, who can offer not only an excellent product, but also a wide presence worldwide. In this regard, creation of a consolidated global business network is one of the key aspects of Haemopharm policy.

Over the years, Haemopharm has developed a network of strategic partnerships and commercial agreements, thanks to which it is now present and active in many countries in the world, including Western and Eastern Europe, North and South America, Australia, the Far East, providing the tools to manage geographical areas representing the largest interest for our business.

Direct presence in Serbia. Quatalia Science d.o.o, headquartered in Belgrade, is a Haemopharm daughter company, that was created to consolidate local business and facilitate penetration into emerging markets. In its turn, Quatalia has numerous marketing authorizations, including cancer treatment, antibiotics and medical devices.

Regulatory affairs - competence and constant update. Both Haemopharm and Quatalia have own Regulatory Affairs departments, that are in charge of supervising for overseeing international Marketing Authorizations, preparing drug dossiers for pharmaceutical products and technical files for CE marked medical devices.

FDA Certification. Obtaining FDA certification, required to commercialize medical devices in the US, represents an important step in Haemopharm's development strategy.

SAFE2®

CRYOPRESERVATION BAGS

ADVATIS

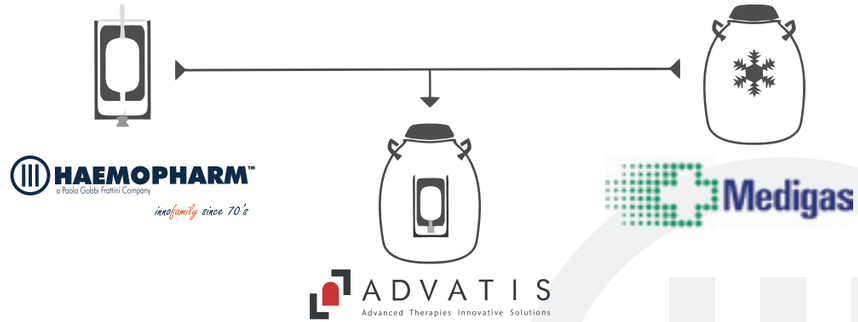
Joint venture with Medigas Italia

A global network of partnerships and business relationships allows Haemopharm to expand its core business and diversify its offering through collaboration with important players in the sector.

In may 2005, Haemopharm signed a cooperation agreement with Medigas Italia S.r.l. for development, production and marketing of the new line of bags for cryopreservation of stem cells and tissues: SAFE2™. The agreement with Medigas Italia opens up new market segments and, thanks to the support of a reliable partner, allows Haemopharm to continue searching for innovations and improvement in the field of cell therapy, in order to produce products that fully meet the strict requirements of customers and end-users.

In 2015, the continuous cooperation between the two companies turns into a contractual joint venture - ADVATIS (Advanced Therapies Innovative Solutions), - which provides the market with innovative solutions in the field of cryopreservation and cell therapy, offering a wide range of products that cover various stages of collection, manipulation and preservation of stem cells and tissues.

With a high level of flexibility and support of an R&D team, ADVATIS is able to offer customized solutions to meet any customer need.



CORPORATE RESPONSIBILITY

Both current and future success of Haemopharm Healthcare is based on a solid foundation of ethical values that run though all daily activities and represent the official operating principles of the company.

Responsibility, ethical approach in work and ability to form genuine partnerships with our clients, respect for people, business transparency, impartiality in the HR management, honesty and clarity of contracts, commitment to the undertaken obligations, compliance with the law and respect for institutions in all countries of the world – these are the core values that are combined with a customer-oriented culture with which Haemopharm establishes synergic and long-lasting collaborations.

Sustainable growth and operating inspire us to keep looking for and finding technical solutions, improving the use of resources and reduce our environmental impact.

haemopharm.it

HAEMOPHARM™
a Paolo Gobbi Frattini Company

HAEMOPHARM HEALTHCARE S.R.L.
COMMERCIAL OFFICE
Viale Lazio, 26
I - 20135 Milano (MI)
Phone +39 02 5513513
Fax +39 02 55191982
info@haemopharm.it
haemopharm.it

PAOLO GOBBI FRATTINI
flexible bags & biotechnology products

PAOLO GOBBI FRATTINI S.R.L.
FACTORY
I - 23030 Tovo di Sant'Agata (SO)
Via Provinciale, 8
Tel +39 0342 771017
Fax +39 0342 771018
info@haemopharm.it
haemopharm.it