CLEANRoom

by Termovent

DTtermo

GROUP OF COMPANIES

INTRODUCTION

More than 20 years of business experience, application of internally developed cutting-edge technology, exceptional engineering personnel and advanced manufacturing practices create excellent foundation of Termovent's production program.

We are committed to creating ideal working conditions with minimal costs and development of products that meet rigorous requirements of today's quality and energy efficiency practices.

While being dedicated to principles of sustainable development, environmental protection, quality and safety, we are following highest quality standards in our daily work and in the future development of our company.

Dušan Perović

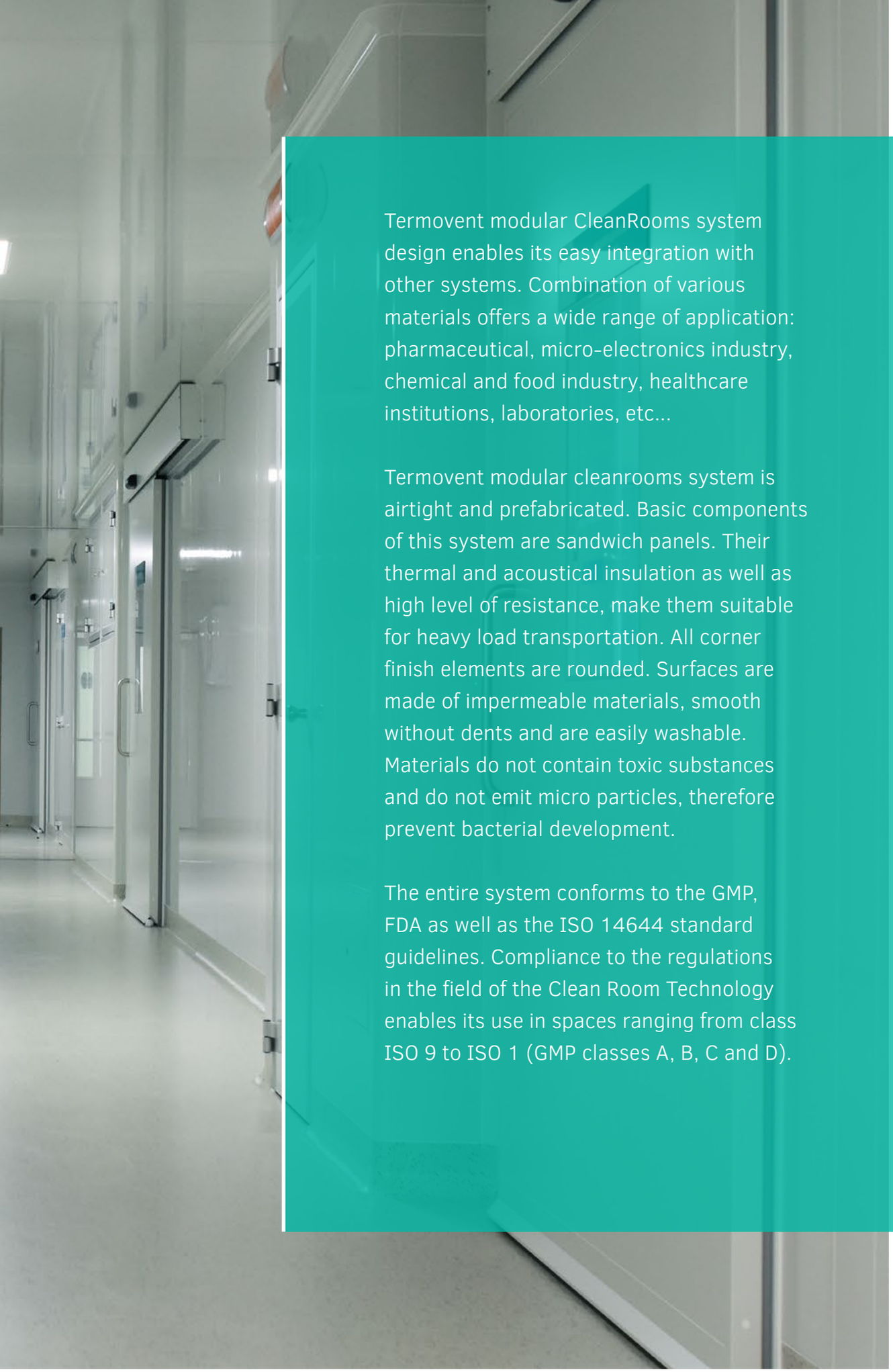
In addition to manufacturing and installation of Air Handling Units, Termovent's production program includes design, production and installation of modular panel system applied in the field of clean rooms technology (GMP classes A, B, C and D).

Termovent's dedication to providing full and complete support throughout all phases of project realization, resulted in development of Termovent's clean space engineering department. In addition to extensive expertise of our engineering personnel we possess all relevant design, production and installation licenses. Finally, our engineers are more than familiar and confer to all valid and mandatory GMP norms and guidelines, references and standards in the field of clean room technologies.

For more than two decades of business practice, Termovent successfully carried out hundreds of projects all over the world. While consistently following industry regulations and respecting clients' business needs, agreed project prices, scope and delivery dates, Termovent generated business relationships and fostered cooperation with the world's most famous pharmaceutical companies such as: Pfizer Global Manufacturing, Purna Pharmaceuticals, Pharmasyntez, Delpharm, Dishman Netherlands, Tube Souples, Zoetis, Bilthoven Bilogicals, Hemofarm, Actavis, Bionika Pharmaceuticals, Wellpharma Medical Solutions

CONTENT

MODULAR CLEANROOM



Termovent modular CleanRooms system design enables its easy integration with other systems. Combination of various materials offers a wide range of application: pharmaceutical, micro-electronics industry, chemical and food industry, healthcare institutions, laboratories, etc...

Termovent modular cleanrooms system is airtight and prefabricated. Basic components of this system are sandwich panels. Their thermal and acoustical insulation as well as high level of resistance, make them suitable for heavy load transportation. All corner finish elements are rounded. Surfaces are made of impermeable materials, smooth without dents and are easily washable. Materials do not contain toxic substances and do not emit micro particles, therefore prevent bacterial development.

The entire system conforms to the GMP, FDA as well as the ISO 14644 standard guidelines. Compliance to the regulations in the field of the Clean Room Technology enables its use in spaces ranging from class ISO 9 to ISO 1 (GMP classes A, B, C and D).

MODULAR CLEANROOM OVERVIEW

A
Wall Panel

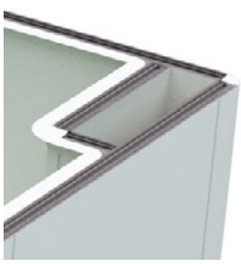
B
Switch / Socket

C
Window

D
Door

E
Pass Box

F
Air Shower



G
Double Wall Extraction

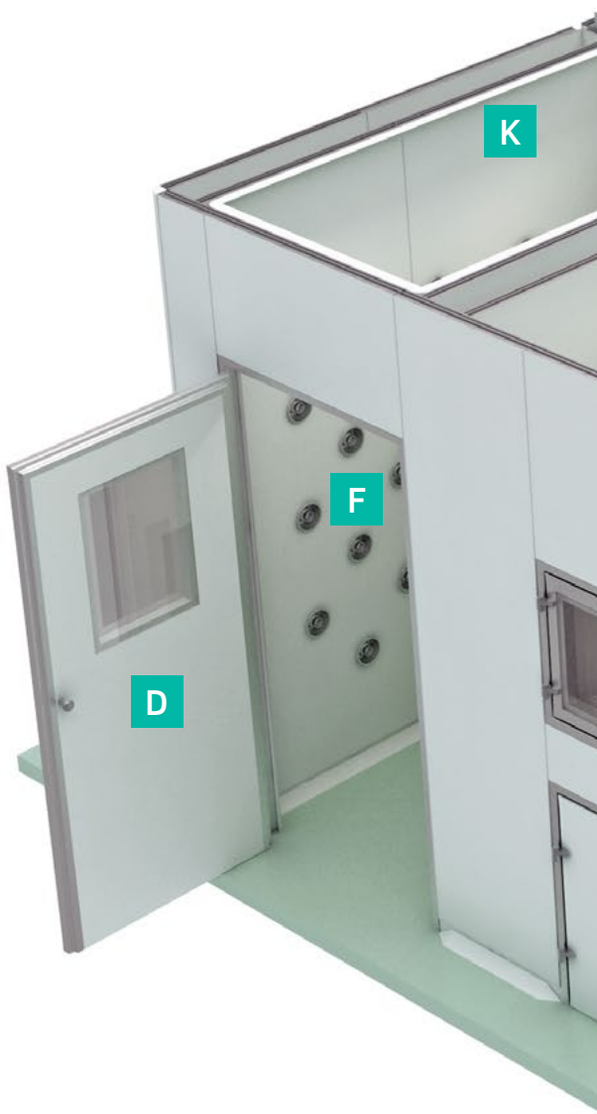
H
Wall Extraction

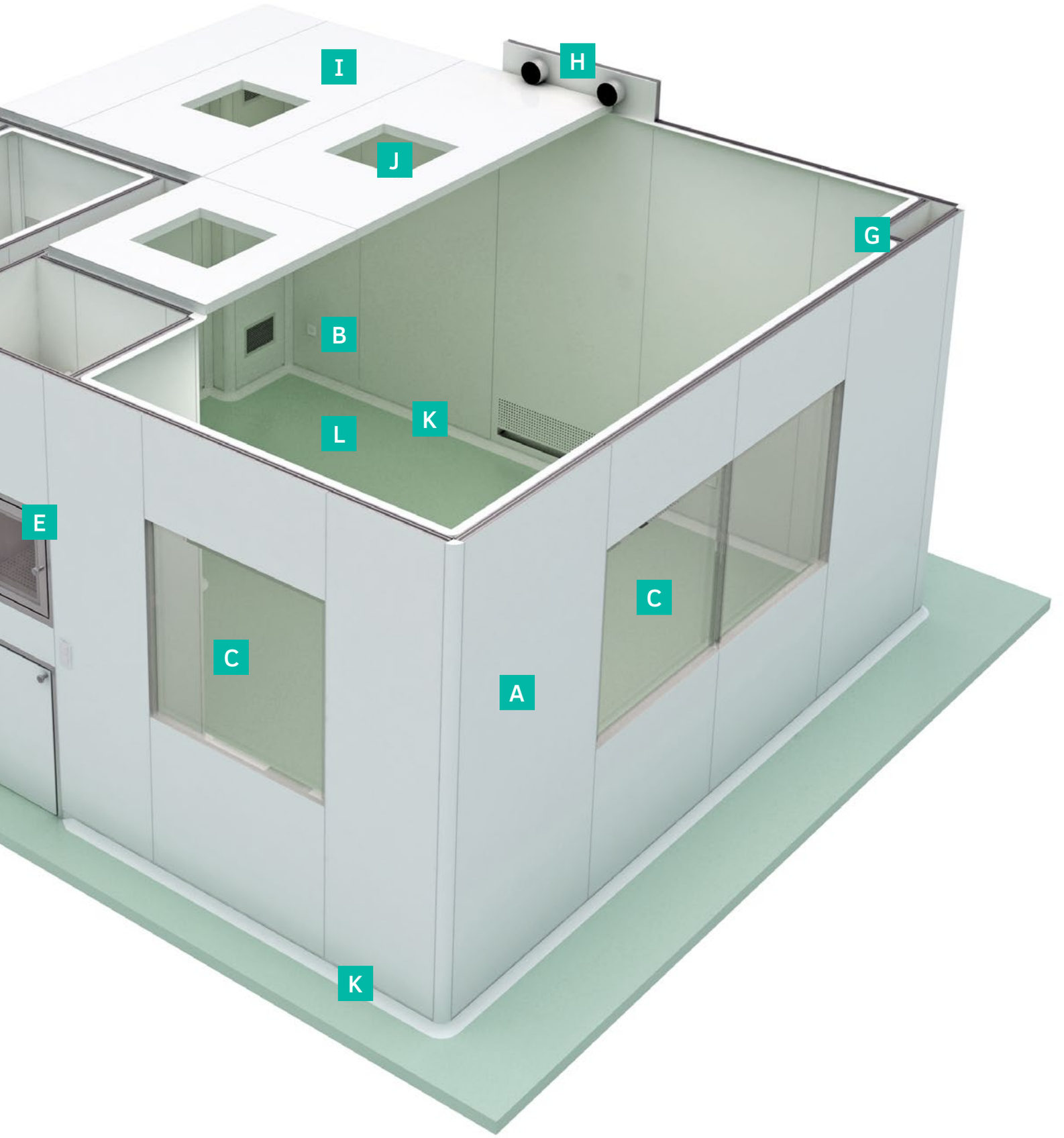
I
Ceiling Panel

J
Reinforced Ceiling Opening

K
Coving

L
Floor

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WALL

Modular design of Termovent Cleanroom Wall panels allows their easy integration with other systems, such as: doors, windows, electrical installation, mechanical installation, plumbing installation, etc. They are designed based on an approved DQ drawing. Coordination with civil, architectural, electrical and mechanical design is of high importance, which involves installation of electrical cable channels, drilling openings and construction of structural reinforcement for lights, grilles, air diffusors, etc. This enables clean, accurate and quick installation. All the joints are sealed with high-quality single-component polyurethane adhesive. Upon the installation, any infiltration of particles into CleanRooms is prevented.

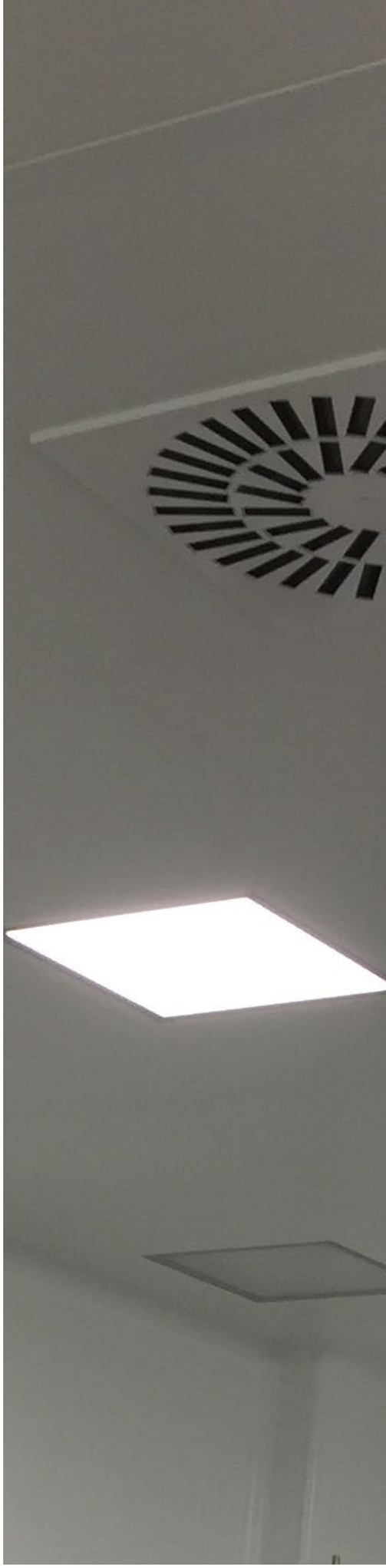
Termovent Cleanroom Wall Panel is made of 62.8mm thick sandwich panel, constructed from aluminum profiles, filled with rock wool insulation, density of 120kg/m3. Pressure resistance is 80kPa, according to the EN 1607. Panel is covered with galvanized metal sheet plates, 0.8 mm thick, painted in RAL9002, 25µm thick layer. Besides the galvanized metal sheets, wall coatings can be made of aluminum or stainless-steel sheets, depending on the room's purpose or requirements.

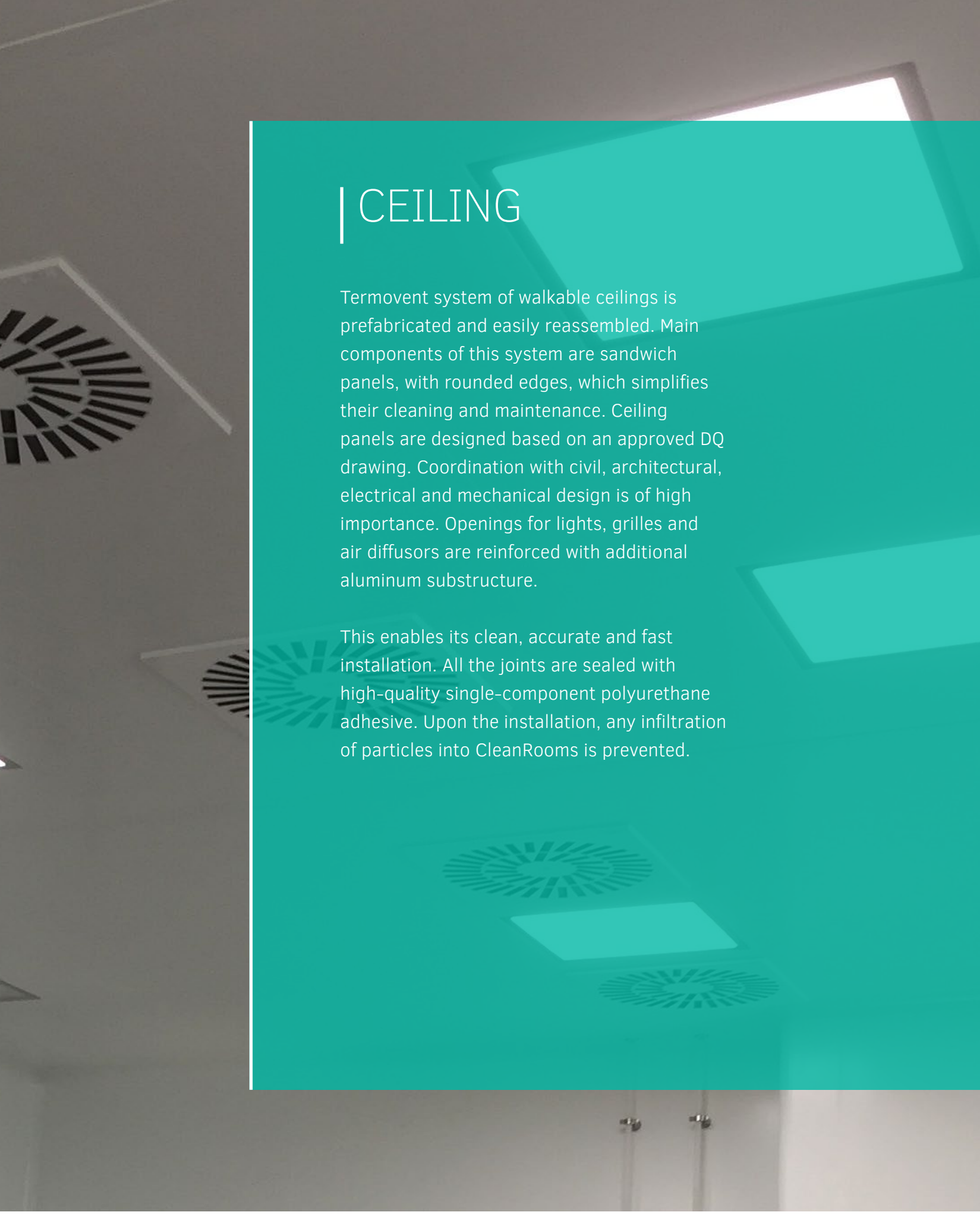
Termovent panels are made in compliance with ETAG 003 thus belong to the highest quality category. Standard module widths are 1.200mm, 900mm, 600mm, 300mm and 150mm, while maximum height is 3.500mm.

Termovent Cleanroom Wall Cladding has thickness of 18mm. Consists of galvanized metal sheet plate, 0.8mm thick, painted in RAL9002, 25µm thick layer. Cladding is filled with 12.5mm thick plasterboard. Standard module widths are 1.200mm, 900mm, 600mm, 300mm and 150mm, while maximum height is 3000mm.

Termovent Cleanroom Ceiling Panel is made of 62.8mm thick sandwich panel, constructed from aluminum profiles, filled with rock wool insulation, density of 120kg/m3. Pressure resistance is 80kPa, according to EN 1607. Panel is covered with galvanized metal sheet plates, 0.8 mm thick, painted in RAL9002, 25µm thick layer. Besides the galvanized metal sheets, wall coatings can be made of aluminum or stainless-steel sheets, depending on the purpose or requirements.

Standard module widths are 1.200mm, 900mm, 600mm, 300mm and 150mm, while maximum height is 3.500mm.

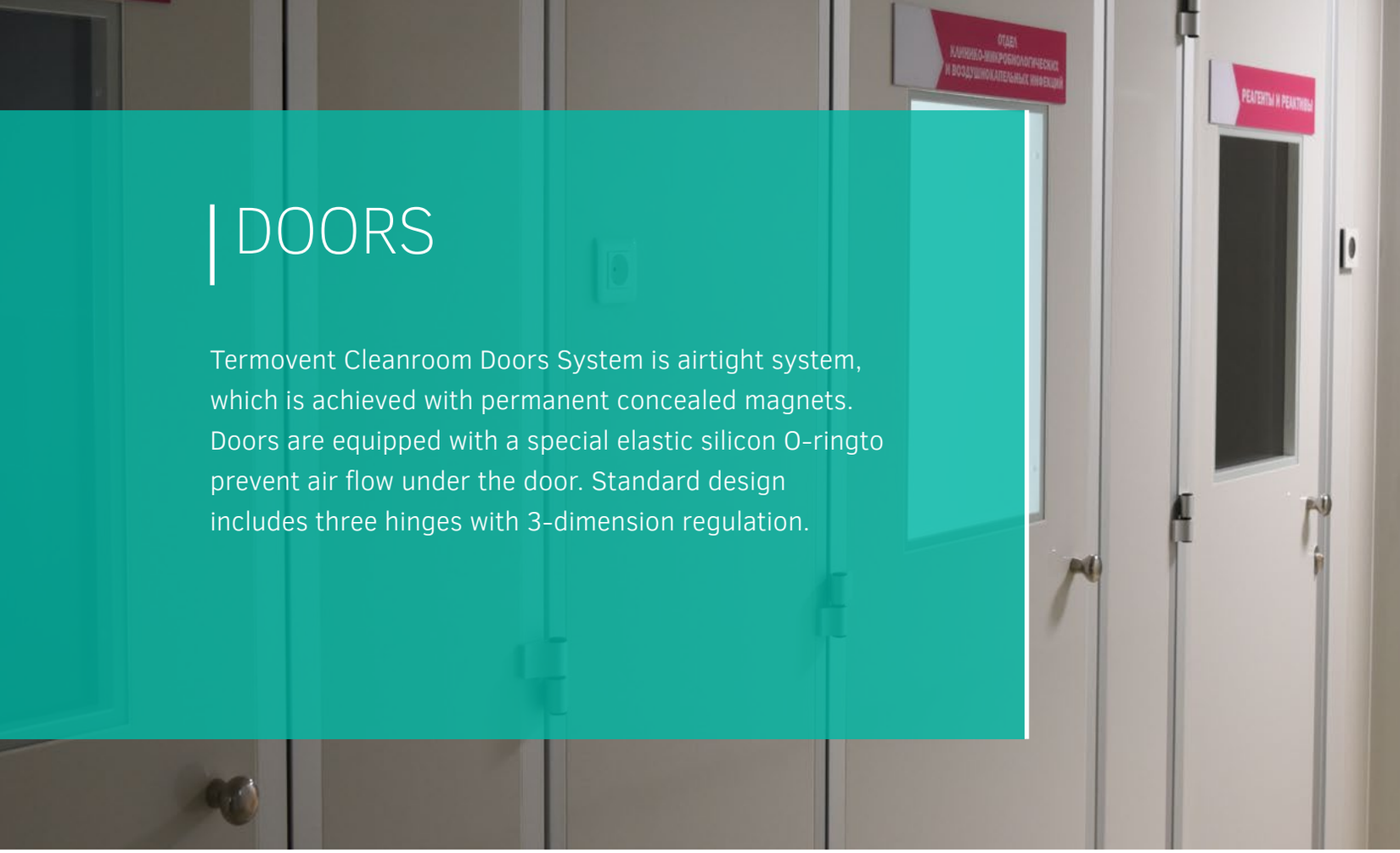




CEILING

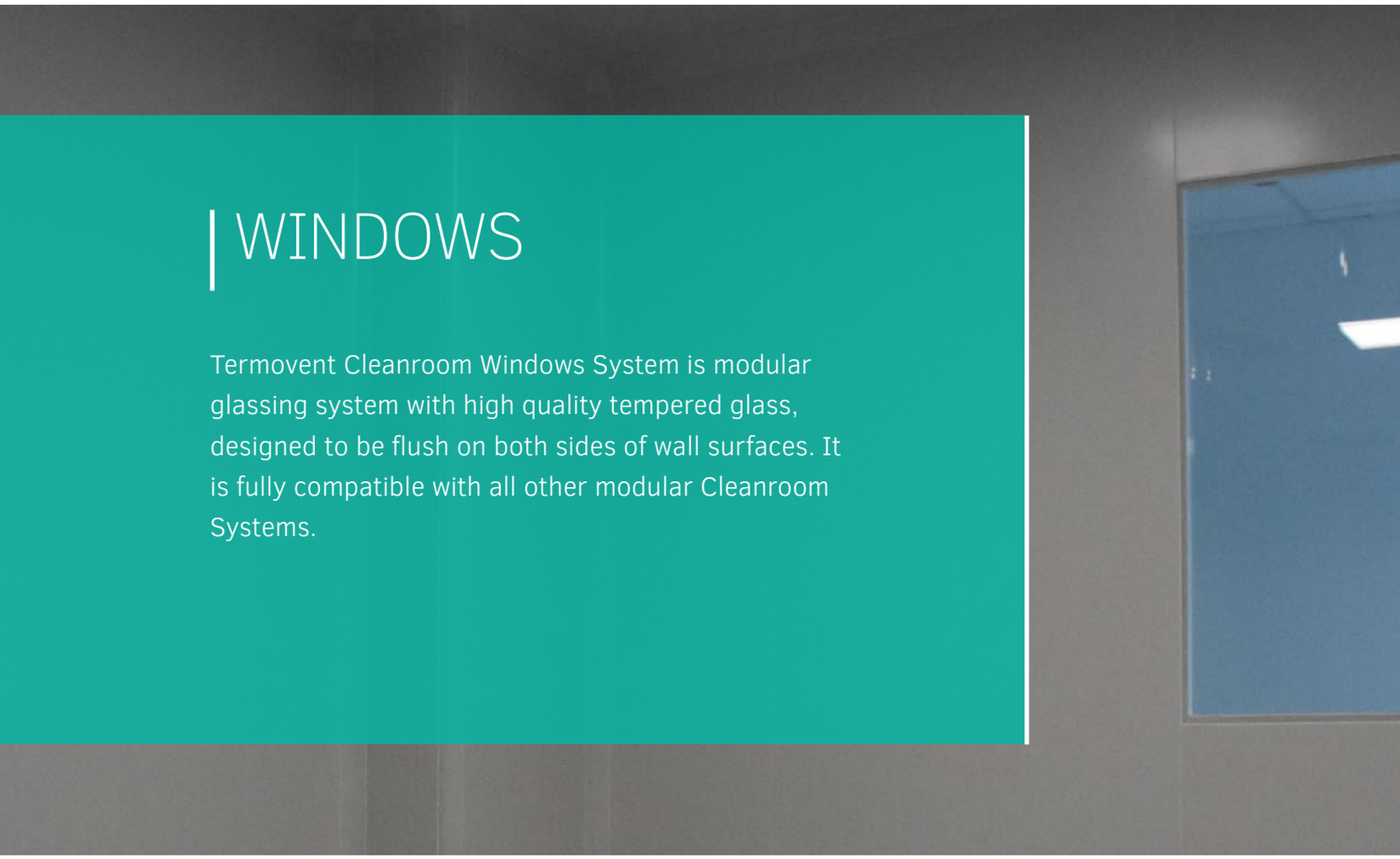
Termovent system of walkable ceilings is prefabricated and easily reassembled. Main components of this system are sandwich panels, with rounded edges, which simplifies their cleaning and maintenance. Ceiling panels are designed based on an approved DQ drawing. Coordination with civil, architectural, electrical and mechanical design is of high importance. Openings for lights, grilles and air diffusors are reinforced with additional aluminum substructure.

This enables its clean, accurate and fast installation. All the joints are sealed with high-quality single-component polyurethane adhesive. Upon the installation, any infiltration of particles into CleanRooms is prevented.



DOORS

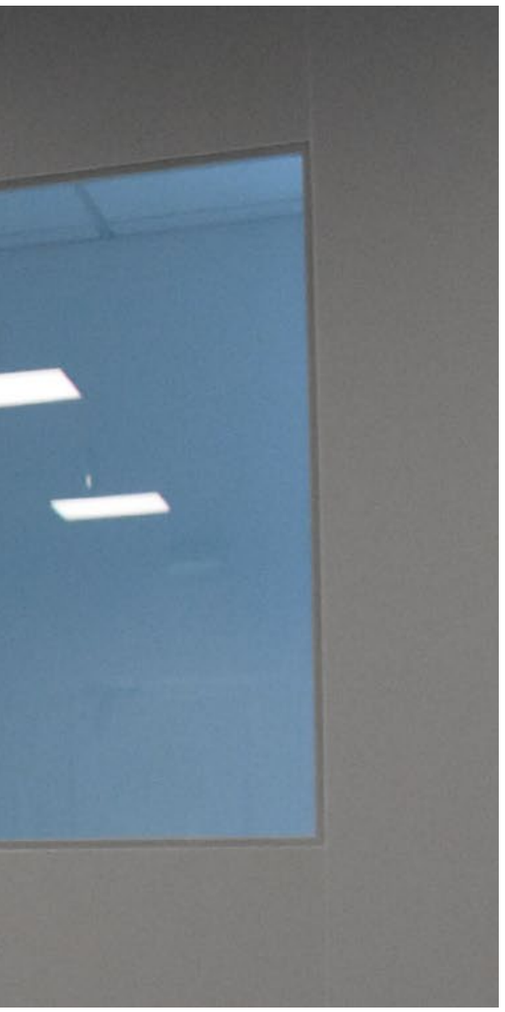
Termovent Cleanroom Doors System is airtight system, which is achieved with permanent concealed magnets. Doors are equipped with a special elastic silicon O-ringto prevent air flow under the door. Standard design includes three hinges with 3-dimension regulation.



WINDOWS

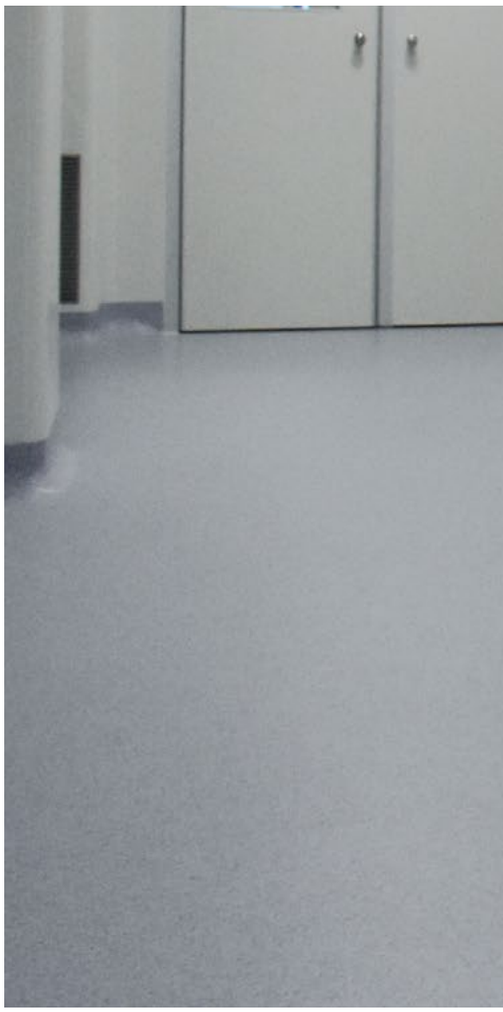
Termovent Cleanroom Windows System is modular glassing system with high quality tempered glass, designed to be flush on both sides of wall surfaces. It is fully compatible with all other modular Cleanroom Systems.

Termovent single or double swing-out Cleanroom Doors are made of cleanroom panels. Internal and external framework is made of anodized aluminum profiles. Panel is constructed from two galvanized metal sheet plates, 0.8mm thick, painted in RAL 9002, 25 µm layer, with interior aluminum frames. Panel is filled with rock wool insulation, density of 120kg/m3. Standard door is equipped with magnets, hinges and stainless-steel door knob. Additional equipment is possible on request.



Termovent Cleanroom Widows are 62.8mm thick panels, consisted of two 6mm tempered glasses. Windows are constructed of interior powder coated aluminum frame.

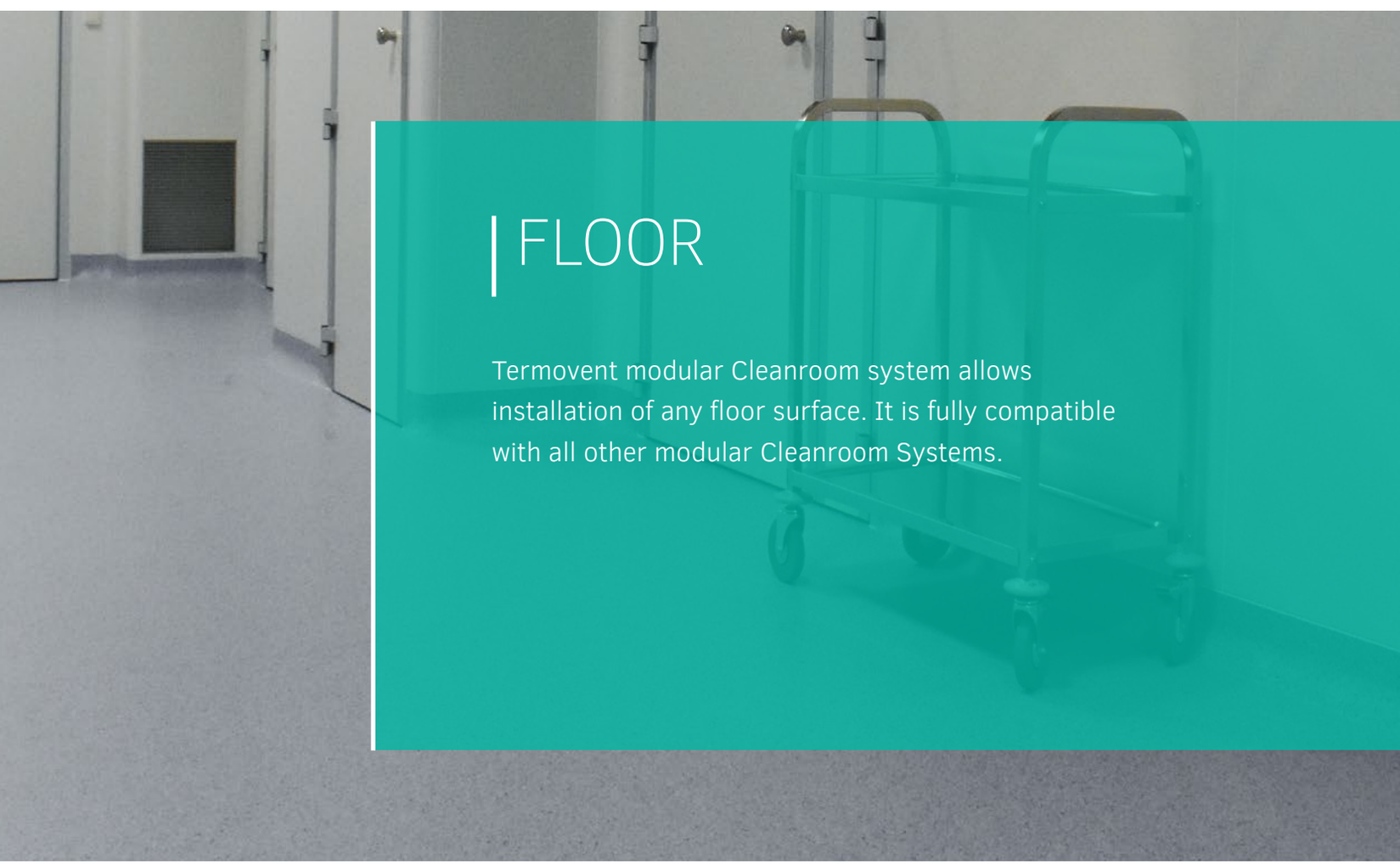
Termovent Coving system is constructed from rounded aluminum profiles, which enables simple contact between floor and all other systems (doors, corners, walls, etc.). System provides easy cleaning and maintenance. Joints are sealed with high-quality single-component polyurethane adhesive. Upon the installation, any infiltration of particles into CleanRooms is prevented.



Termovent Cleanroom Floors System can be covered with PVC or Epoxy coating. In explosive rooms, floors are made of antistatic conductive materials and all corner elements as well as wall panel guides are connected and grounded. Upon specific request, rooms with higher noise control can be equipped with rubber material floors.

COVING

Termovent modular component Coving System is prefabricated and easy to reassemble. It is fully compatible with all other modular Cleanroom Systems. Structure of Termovent Coving System enables its installation as an integral part of Termovent Cleanroom Walls, Ceilings and Floors System.



FLOOR

Termovent modular Cleanroom system allows installation of any floor surface. It is fully compatible with all other modular Cleanroom Systems.

PROJECT REALISATION PHASES

Customization of investor’s requirements

Project management team

Conceptual design

Architectural design

Synchronization plan

Project design and detailed drawings

Detailed timetable of production and installation

Production and installation

Qualification and validation

Project handover

Maintenance of MCR System

Termovent Modular Cleanroom System design is based on technological, architectural and installation principals, such are: electrical, mechanical, plumbing and sewerage plans. With detailed planning, designers must take into consideration the purpose of the cleanrooms, its technology, as well as people's presence in production processes.

Shape and dimensions of rooms are defined in the architectural design. Classification of the room are defined by the purposes, ranging from class ISO 9 to ISO 1 (GMP classes A, B, C and D).

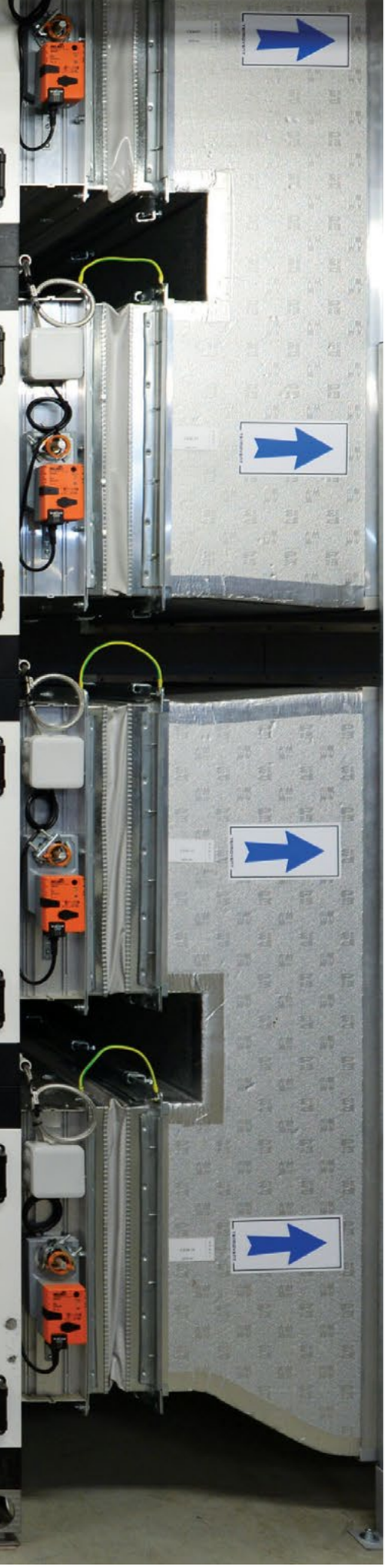
Compliances with installation project involve the coordination with HVAC and electrical systems (drilling openings in construction for luminaires, grilles, air diffusers, and other needed technologies).

With consistent commitment with investors' requirements, we can realize every project according to the timetable, at quoted price.

HVAC and BMS turnkey system

HIGH LEVEL OF RELIABILITY

Hands-on experience, along with high-quality and reliability of HVAC and BMS application (GMP classes A, B, C and D), have led Termovent to becoming a strategic partner of the world's leading pharmaceutical manufacturers, such as: Pfizer Global Manufacturing, Sterop Laboratories, Purna Pharmaceuticals, Delpharm, Dishman Nedherlands, NV Tube Souples, Bilthoven Biologicals, Hemofarm, Actavis, ...



HVAC System Design

Within our projects we provide required air quality according to the room classification, in compliance with GMP requirements, which in addition to the air filtration, require a constant number of air changes as well as maintenance of pressure cascade between adjacent spaces. Moreover, temperature and air humidity within a narrow band, defined velocity and type of airflow, are accomplished within the classification requirements.

Equipment manufacturing, delivery and installation

Termovent specializes in **installation** of HVAC applications in the field of clean room technology as well. Besides production of modular component system for clean rooms, Termovent is a producer of HVAC equipment and process systems. Hygienic version of air handling units is an integral part of Termovent's production program.

Central automation system manufacturing, delivery and installation

Automation of the system provides monitoring and control of all important parameters: temperature, humidity, pressure and air volume. The entire system is built in compliance with GMP requirements.

Equipment Commissioning and Start-Up and Measurement with Calibrated Instruments

Termovent provides design, delivery and installation of HVAC management systems, peripheral automatic elements, control panel cabinets and performance adjustment of automatic control elements and electric motor drives. The offer also includes visual and functional inspection of the automatic control equipment, DDC controller programming and adjustment of the system for optimal start and operation mode.

Preparation of validation documents

Part of Termovent's complete business offer is preparation of validation documents in accordance with GMP requirements: validation plan (VP), design qualification (DQ), functional design specification (FDS), hardware design specification (HDS), software design specification (SDS), protocols with attachments (IQ, OQ).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REFERENCES

- **ADOC**, Belgrade, Serbia, Secondary packaging
- **BESINS HEALTHCARE**, Drogenbos, Belgium, Production of medications
- **BILTHOVEN BIOLOGICALS**, Bilthovent, Netherlands, Produciton of vaccines
- **BLAGOLEKS**, Bijeljina, Bosnia and Herzegovina, Production of medications
- **DELPHARM**, Drogenbos, Belgium, Production of medications
- **DIJAGFARM**, Belgrade, Serbia, Pharmaceutical products warehouse
- **DISHMAN NETHERLANDS**, Veenendaal, Netherlands, Highly contaminated GMP laboratory
- **FARMIX**, Belgrade, Serbia, Pharmaceutical products warehouse
- **FM FARM**, Subotica, Serbia, Production of animal drugs
- **HABIT FARM**, Ivanjica, Serbia, Production of medications
- **HEMOFARM**, Vršac, Serbia, Production of IV solutions
- **ICN**, Zagarač, Montenegro, Production facility for solid forms
- **JUGOREMEDIJA**, Zrenjanin, Serbia, Microbiological laboratories
- **KATOD**, Novosibirsk, Russia, Sterile production of optical fibres
- **KELA**, Hoogstraten, Belgium, Production of animal drugs
- **MEDICINES AND MEDICAL DEVICES AGENCY OF SERBIA**, Belgrade, Serbia, Pharmacological laboratories
- **NI MEDIC**, Belgrade, Serbia, Production of solid and liquid forms
- **NV TUBE SOUPLES**,Ternat, Belgium, Production of PVC and aluminium tubes for toothpaste, creams and gels
- **PFIZER ANIMAL HEALTH SA**, Louvain La Neuve, Belgium, Production of animal drugs
- **PFIZER MANUFACTURING BELGIUM NV**, Puurs, Belgium, Production of medications
- **PHARMANOVA**, Belgrade, Serbia, Production of medications
- **PHOTON OPTRONICS**, Niš, Serbia, Sterile production of optical fibres
- **PROTON**, Belgrade, Serbia, Production of solid and liquid forms
- **PURNA PHARMACEUTICALS**, Puurs, Belgium, Production of medications
- **RASAN PHARMACEUTICALS**, Suleymaniyah, Kurdistan (Iraq), Production of medications
- **SLAVIAMED**, Sremska Mitrovica, Serbia, Production and packaging of ointments and creams
- **SMB**, Marche, Belgium, Production of pharmaceutical products
- **STEROP**, Brussels, Belgium, Production of medications
- **THE INSTITUTE OF VIROLOGY, VACCINES AND SERRA –TORLAK**, Belgrade, Serbia, Room for ampoule filling
- **VARUS (MERCK)**, Skoplje, Macedonia, Production of medications
- **WELLPHARMA MEDICAL SOLUTIONS**, Abu Dhabi, UAE, Production of IV solutions
- **ZDRAVLJE (ACTAVIS)**, Leskovac, Serbia, Production of medications
- **ZOETIS**, Louvain La Neuve, Belgium, Reconstruction of the HVAC system for LYO rooms
- **KATOD**, Novosibirsk, Russia, Production of Night-Vision equipment
- **FARMASINTEZ**, St. Petersburg, Russia, Production of medications

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