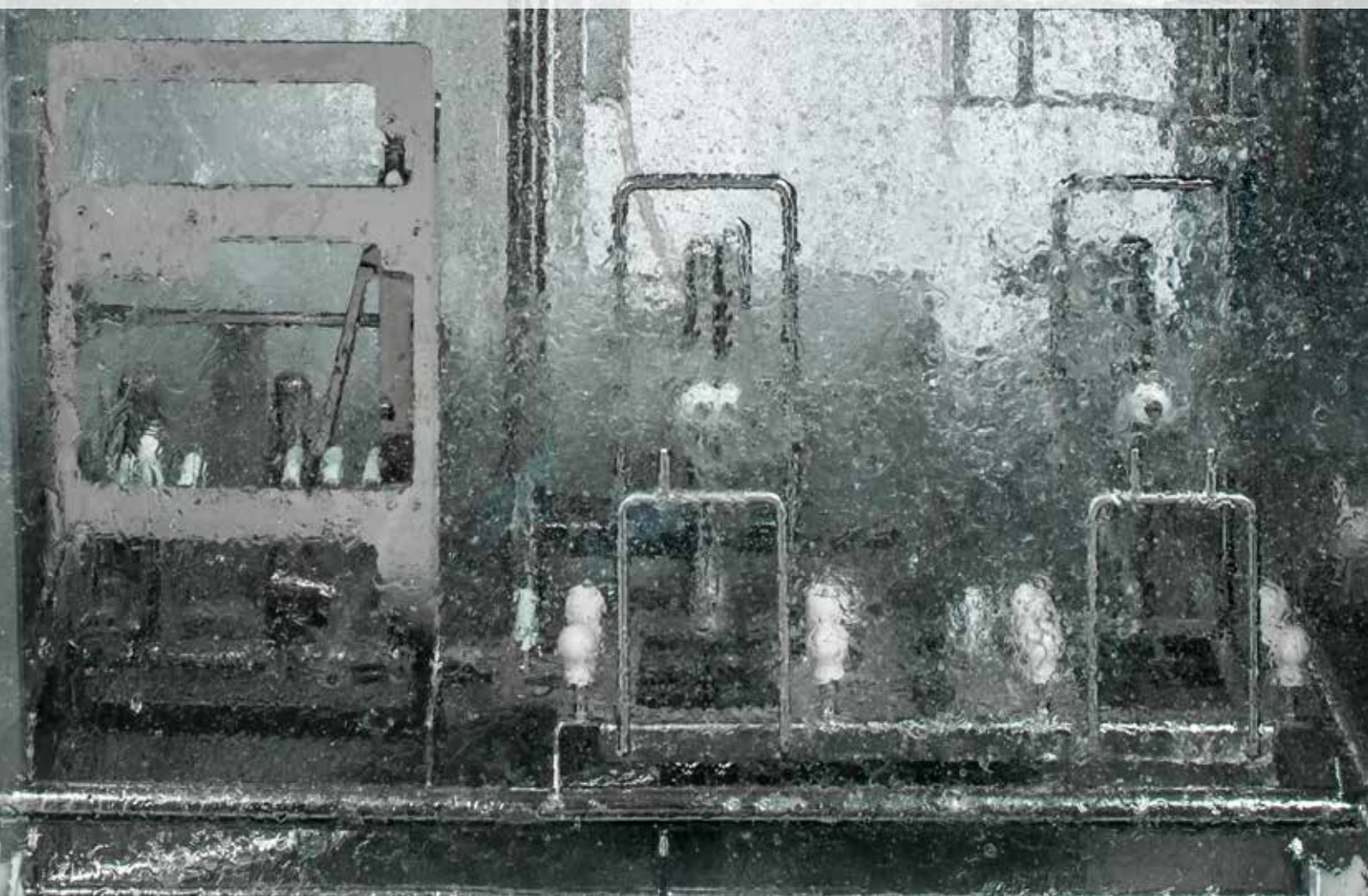
The cleaning solution

for validating your sterile processes
in the **safest**, **easiest** and **fastest way**.



100+ years of Mastery in Pharma and Excellence manufacturing configurable washers finally converge into FIT.

Fedegari and IWT now combine their strenghts to present an effective solution to the dynamic world of Pharma Business.

The alliance empowers customers to access Safe, Easy and Quick solutions for sterile production, when time to market is a challenge and drives decisions.

SAFE

Fit your commitment
Fit your processes

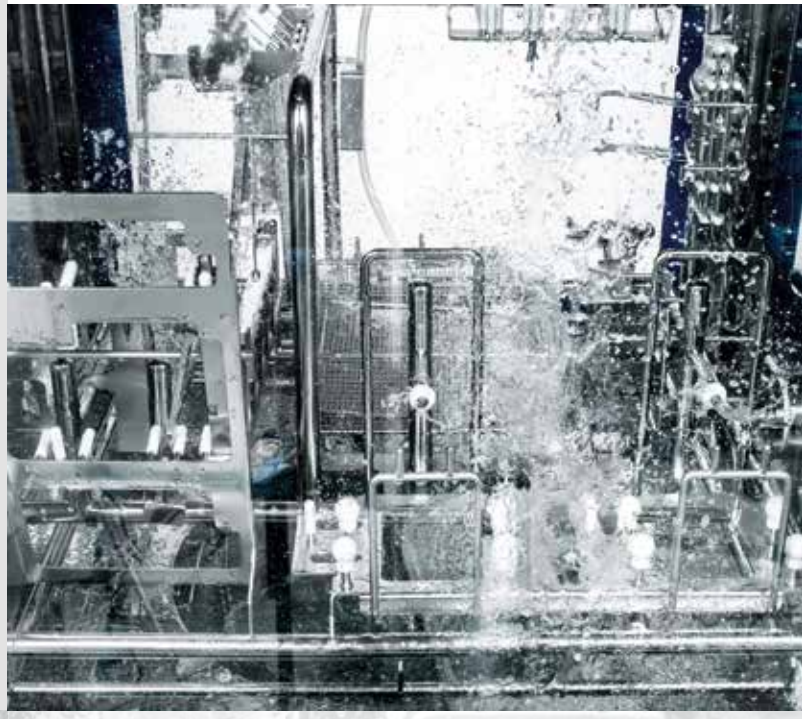
Ensuring the safety and efficacy of the sterile products being manufactured, while establishing robust assurance of contamination prevention

Validated washing cycle in a fully ASME BPE machine

FIT designing is managed in accordance with Quality Risk Management (QRM) principles to provide a proactive means of identifying, evaluating and controlling potential risks to quality. Accurate Contamination Control Strategy (CCS) can be easily granted by the automatic cleaning operation.

Complete isolation to preserve pharma grade air quality

Maintaining the quality of air is of utmost importance, especially for the production of sterile products. The HEPA filtration on the exhaust ensures that the chamber is completely isolated from external environments, thereby preventing any potential compromise of the pharmaceutical grades on the loading and unloading sides.



EASY

Fit your space
Fit your operations

Simplifying Annex 1 compliance through the implementation of validated washing is our forward-think

The most compact footprint ever

Flexibility, Configurability, and minimal interference with the existing production system: FIT aids bio-pharmaceutical companies in overcoming space constraints within their facility layouts by offering a cGMP-compliant washing machine with a reduced footprint by 30% to 50%*.

* compared to main industrial washing machines on the market

Functional design for cGMP Technology on hand

FIT enhances operator safety and ergonomics by prioritizing usability and simplicity in its industrial design.
This design automates tasks and intuitively guides the operator through the activities they must perform.

FEDEGARI iwt

QUICK

Fit your schedule
Fit your business

Unlocking the full potential of the of automated cleaning solutions in the fastest way propelling your business

Fast track delivery to expedite go-to-market

We are aware biopharmaceutical companies are challenged by the development of innovative drugs: FIT not only meets expectations but also ensures compliance with Annex 1 regulations - all within a lead time of just 5 months.

Designed for modular and flexible configuration

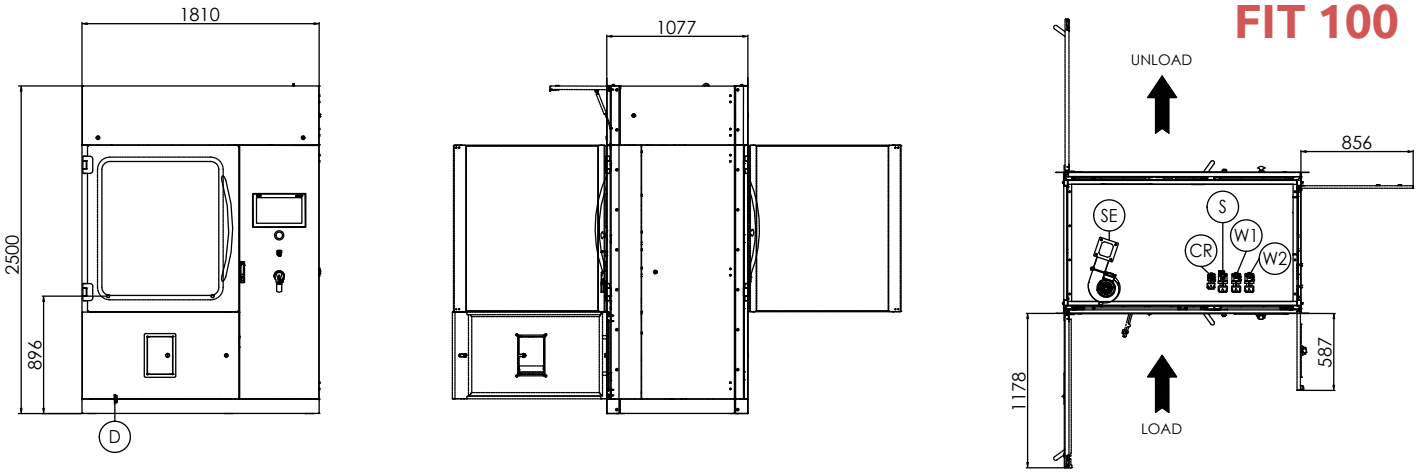
A modular platform designed to guide when selecting and managing the cleaning system. A unique product, composed by the features essential to your own sterile process, for a conscious choice according to your operations.

COMPLIANCE TO DIRECTIVES AND STANDARDS

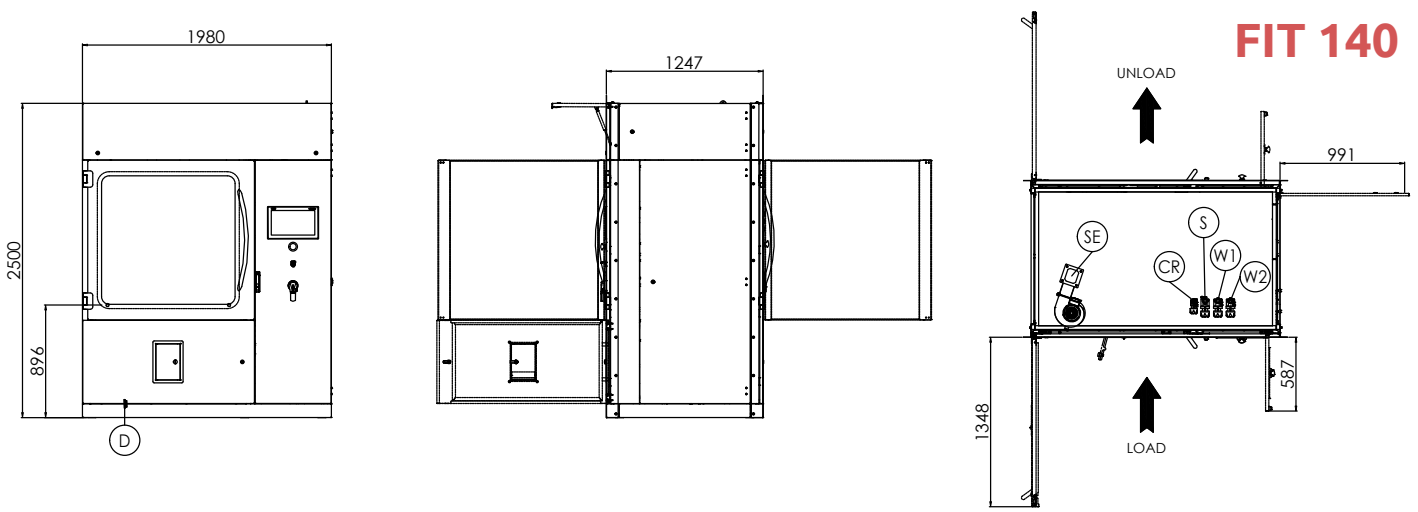
cGMP	Current Good Manufacturing Practices
GAMP5	Good Automation Manufacturing Practices
ISPE Baseline Guides	International Society for Pharmaceutical Engineering
ASME-BPE	American Society of Mechanical Engineers - Bioprocessing Equipment
ASNT SNT-TC-1A	Personnel Qualification and Certification in Non-destructive Testing
CFR Title 21, Part 210	Current Good Manufacturing Practices in manufacturing, processing, packing, or holding of drugs
CFR Title 21, Part 211	Current Good Manufacturing Practices for finished Pharmaceuticals
CFR Title 21, Part 820	Quality System Regulation
CFR Title 21, Part 11	Electronic Records: Electronic Signature
2006/42/EC	Machinery Directive
2014/35/UE	Low Voltage Directive
2014/30/UE	EMC Directive
UNI EN ISO 12100	Safety of machinery - General principles for design. Risk assessment and risk reduction
CEI EN 60204-1	Safety of machinery - Electrical equipment of machines. General requirements
UNI EN ISO 13849-1	Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design
UNI EN ISO 13732-1	Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces

MODEL	Nominal Chamber Dimensions (mm)	Nominal Chamber Volume (l)
FIT-100	959 x 1013 x 1089	1058
FIT-140	1129 x 1183 x 1089	1454

FIT 100



FIT 140



UTILITIES	CONNECTION	REQUIREMENTS	INDUSTRIAL STEAM HEATING	ELECTRICAL HEATING
Electrical supply	Electrical cabinet	Voltage and frequency: Type: Power required: Circuit Breaker: Suggested Line fuse:	400 V 50Hz 3 phases+neutral+earth 8,5 kW 40 A 50 A	400 V 50Hz 3 phases+neutral+earth 50,5 kW 125 A 160 A
Compressed air	Ø 10mm	Dynamic pressure: Quality: Min flow rate: Min flow rate (Single Pass Rinse option):	6 bar filtered, dry and oil free 50 Nl/min @ 6 bar 650 Nl/min @ 6 bar	
Water 1 Supply	Tri-Clamp DN22	Dynamic pressure: Static pressure: Supply temperature: Supply flow rate: Max Hardness:	2-4 bar max 8 bar 15°C<T<85°C 3600 l/h (60 l/min) 100ppm of $CaCO^3$	
Water 2 Supply (Single Pass Rinse option)	Tri-Clamp DN22	Dynamic pressure: Static pressure: Supply temperature: Supply flow rate:	2-4 bar max 8 bar 15°C<T<85°C 3600-6000 l/h (60-100 l/min)*	
Industrial Steam	Tri-Clamp DN22	Dynamic pressure: Static pressure: Supply temperature: Min flow rate:	3-5 bar max 6 bar Filtered, dry and saturated 110 kg/h	
Condense return	Tri-Clamp DN10	Min flow rate: Max back pressure:	110 kg/h 1 bar	
Exhaust	Flange Internal Ø 134mm	Min flow: Static pressure: Max ductwork resistance:	1600 m^3/h 650 Pa 300 Pa	
Floor Drain	Tri-Clamp DN50	Min flow rate:	2 l/s	
Data management	RJ45 Ethernet socket			

* The actual flow requirement in highly influenced by the cleaning rack load density

WEIGHT	FIT 100	FIT 140
Empty	1600 kg	1800 kg
Operating (Max)	2000 kg	2200 kg

FEDEGARI HEADQUARTERS
Fedegari Autoclavi SpA
SS 235 km 8 - 27010 Albuzzano (PV) - Italy
T +39 0382434111
F +39 0382 434150

OUR OFFICES WORLDWIDE

ITALY

Fedegari Autoclavi SpA
SS 235 km 8
27010 Albuzzano (PV) - Italy

T +39 0382434111

fedegari@fedegari.com
fedegari.com

Fedegari Autoclavi SpA
Via Bruno Pontecorvo, 18
00012 Guidonia Montecelio (RM) Italy

T +39 06 90532475

fedegari@fedegari.com
fedegari.com

SWITZERLAND

Fedegari (SUISSE) SA
Via alla Gerra, 11
6930 Bedano

T +41 91 9352090

info@ch.fedegari.com

BELGIUM

Fedegari Europe SA-NV
Av. J. Wybran 45B
1070 Brussels
T +32 25201150

info@eu.fedegari.com

GERMANY

Fedegari GmbH
Corneliusstraße 18 -
60325 Frankfurt am Main

T +49 69 907466200

info@de.fedegari.com

CHINA

Shanghai Fedegari Trading Co., Ltd
SML Center,
XuJiaHui Road 610,
Room 3005
Huangpu District, Shanghai
200025

T +86-21-60390739

info@cn.fedegari.com

SINGAPORE

Fedegari Asia Pte. Ltd.
438° Alexandra Road
#01-07/08 Alexandra
Technopark, Singapore 119967

T +65 6 3164761

info@fedegariasia.com

JAPAN

Fedegari Japan K.K.
3F Enokizaka Building,
Akasaka, 1-12-12, Minato-ku,
Tokyo 107-0052

T +81 3 35601241

info@fedegariasia.com

USA

Fedegari Technologies, Inc.
18960 Sellersville, PA

T +1 215-453-0400

info@fedegariusa.com

RUSSIAN FEDERATION

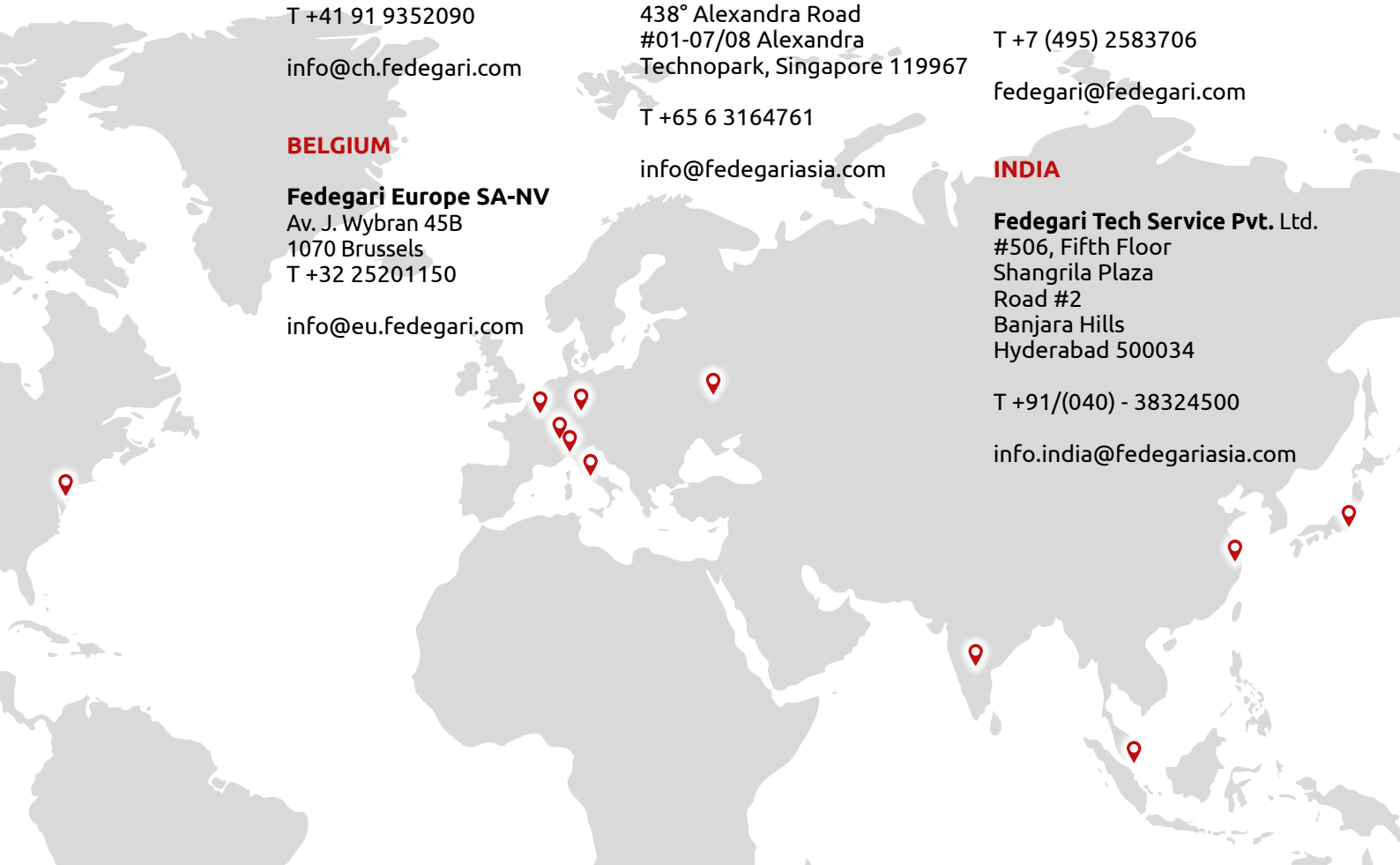
Fedegari Rus OOO
Varshavskoe Chaussee 125D
Corp.2, Of.3,
117587, Mosca

T +7 (495) 2583706

fedegari@fedegari.com

INDIA

Fedegari Tech Service Pvt. Ltd.
#506, Fifth Floor
Shangrila Plaza
Road #2
Banjara Hills
Hyderabad 500034

T +91/(040) - 38324500

info.india@fedegariasia.com