

**Highest productivity and flexibility
in mechanical washing**



PH WASHER

Perfect hygienic design for all
life science applications



Core competencies for successful cooperation



Washer and sterilizers

- Washer and sterilizers developed and built according to customer requirements
- highest process, user and environmental safety
- high machine reliability and plant availability through proven product design
- continuous development to increase usability and connectivity



Application technology competence

- Customized quality solutions – that is our guiding principle. Highest flexibility, low risk of change and fast realization are our strengths.
- Competent field experts will be happy to advise you and offer you a tailor-made solution that is perfectly suited to your application
- The machines are adapted to your specific local conditions and comply with worldwide specifications



Project Management

Our modern project management can be described in three words:

- Pragmatism – single-minded and focused
- Proximity – always in contact and at the pulse of the customer
- Commitment – we give our best so that your goals are achieved



Qualification services

- experienced full-service provider including qualification and validation
- consistently professional risk management and a conclusive clear workflow
- extensive product competence for optimized functionality and cost efficiency
- comprehensive documentation, solid data integrity and full compliance with legal requirements



Life-Cycle-Management

- Full life cycle management from the initial concept idea through production, qualification, maintenance and service to retrofit – everything from one source
- local service network to guarantee you the highest machine uptime

The Belimed Life Science PH Family

Cleaning systems from 1.5 m² floor area to 4.8 m² or can it be a special size? In any case the right one is there!

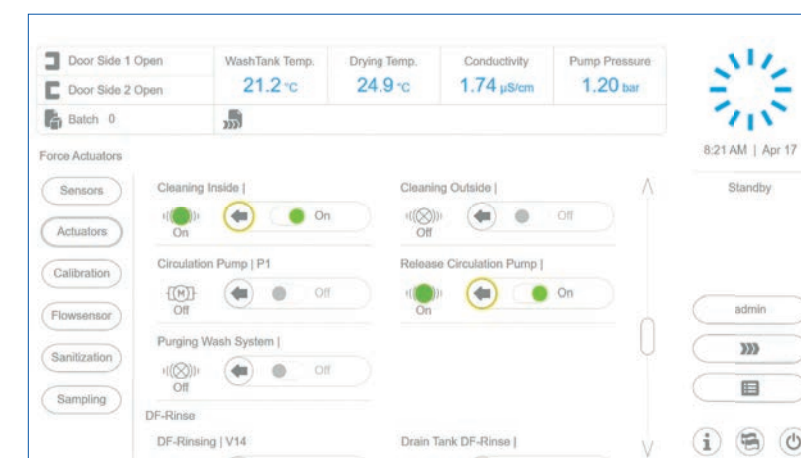
Belimed Life Science washing systems are characterized by:

- the use of stainless steel AISI 316L for the washing chamber and piping
- Use of established and reliable components
- hygienic design of the complete system both in the washroom and outside

The PH Washers offer a wide range of possibilities for:

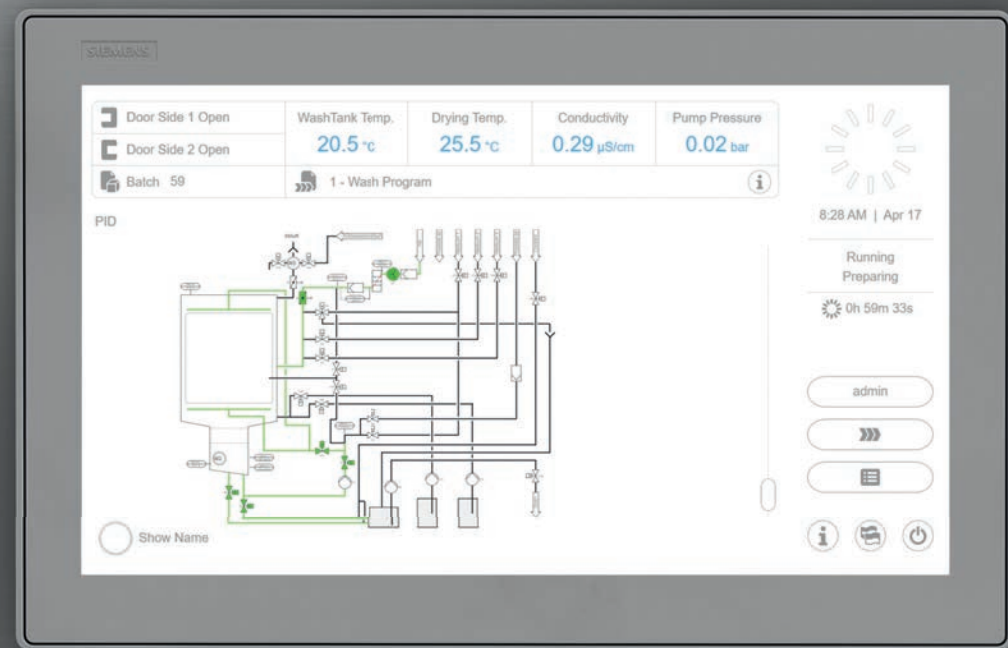
- energy saving
- Automation
- Digitization

Contact us and we will be happy to show you the tailor-made possibilities.



What do all Belimed Life Science PH washer have in common? The B-Touch – safe control by fingertip

For all Belimed Life Science PH Washer the most modern control systems from Siemens or Allen Bradley is used. The HMI is intuitive to use and allows access to all routine operations with just a few clicks. All relevant process data are visible at a glance. Through the simple operation individual recipes can be programmed and stored very easily. Additionally the B-Touch offers interfaces to MES/SCADA systems to integrate the system into a network.



The right solution for every application – The new washer generation

It's good when innovation has a strong foundation. Just like the new Belimed Life Science washers, which are based on leading technology and decades of experience.

With the PH 8x0.2 series, Belimed Life Science offers a family of washers that are optimally adapted to the rational functional sequence in a professional pharmaceutical process.

- uniform technical concept based on many years of experience
- Combination of highest possible standardization and great flexibility for individual customer requirements
- Modular principle to select components according to customer requirements
- UL/CSA/CE versions possible

The PH 8x0.2 washers benefit from a uniform washing and machine concept and differ mainly in the size of the chambers and thus in the storage capacity of wash items per batch.

- PH 820.2, PH 820.2H and PH 840.2 have one rotating washing arm at the top and bottom of the chamber.
- The PH 860.2 and PH 860.2L are each equipped with two washing arms due to the longer chamber design. The overlapping rotation ensures an uninterrupted spray surface.

Design options

- 5 standard chamber sizes
- Systems with special dimensions on request
- 1 or 2 doors
- Maintenance room on the right or left
- Rack specific to the wash item
- Installation in clean rooms with gastight partition wall

Field of application

For washing and drying of:

- Bottles (e.g. bulkhead)
- Tray plates
- Jugs
- Funnels
- Machine parts
- Hoses
- Fittings
- Barrels
- Containers
- ... and much more

B-Touch – visibly and noticeably more operating safety

User interface

The B-Touch HMI is intuitive to use and all routine operations can be reached with just a few clicks. This not only makes work easier, but also reduces operator errors and increases productivity.

Application Control

The B-Touch system control is based on current Siemens or Rockwell SPS systems. An industrial PCA serves as a HMI, which provides all necessary functions for connection to process control systems. The HMI was created with VisiWin, which reduces additional license fees.

Software

The B-Touch software was created and tested according to the GAMP5 standards for software validation. The relevant documents are included in the system documentation. All technical requirements for use according to 21 CFR Part 11 or Annex 11 are available for audit trail, electronic signatures and data security according to the ALCOA Plus principle





Reliable process control

The high operational reliability of Belimed Life Science washers are based on the exclusive use of materials and components of the highest quality and decades of experience.

Materials/Components

Without exception, the materials and components used are produced by renowned manufacturers. They fulfill the highest demands on quality and durability.

- Media-carrying parts such as chamber, tank, piping and pumps are made of AISI 316L.
- Frame and external cladding in AISI 304
- Components with FDA approval
- Seals made of EPDM
- optionally with material test certificate (3.1)
- optional USP Class VI certificate

Specific material requirements can be considered by a large number of options.

GMP rinsing/drying

Washing, rinsing and drying are carried out via a One-pipe system. Optionally, a non-recirculated final rinse directly from the supply line is available (Direct Final Rinse). A strong high performance drying unit and the tight wash rack connection coupling ensure an optimal Drying result.

Process control

The reproducibility of the washing result is guaranteed through the permanent monitoring of all relevant process parameters. For this purpose, an extensive sensor system for measuring the cycle data is available:

- detergent concentration based on flow- and optional conductivity measurement
- Pressure monitoring of all washing and rinsing cycles
- Temperature control with PT-100 sensor, class A
- Conductivity monitoring of the final rinse

Qualification

The optional technical documentation from Belimed Life Science contains a comprehensive and clearly arranged collection of documents that can be used directly for qualification:

- documentation (DQ, IQ, OQ, FAT, SAT)
- Welding book
- Video endoscopic examination of the piping
- Cleaning test with Riboflavin

Pharmaceutical design

Design requirements, which are derived from customer needs in pharmaceutical applications as well as resulting from the latest FDA, GMP and GAMP guidelines have been consistently implemented in the development of the PH 8x0.2 series.

The gap and dead space free wash chamber design with rounded corners is of particular importance: It efficiently prevents of cross-contamination. Dirt and deposits are avoided in the machine right from the start of the washing process.

Execution

- The maintenance-friendly, integrated Service room enables the accommodation of all media connections as well as the stocking of the cleaning containers
- Machine cladding made of very smooth, oil-ground stainless steel sheets
- Horizontal sliding glass doors with inflatable seals and a contamination-free, electric linear or friction wheel drive allow the visual control of the washing process and provide a reliable check of the tightness and accuracy of the washing process.
- Wash chamber and tank interior in mirrored sheet metal design ($Ra \leq 0,4 \mu m$) with round corners (radius R20) as well as ground and polished chamber welds ($Ra \leq 0,8 \mu m$)
- all surfaces with product contact with inclination (chamber roof, chamber floor, piping)
- free of dead spaces, gaps. No screws in the chamber



The patented connection coupling with special sealing mechanism ensures a pressure-constant, leak-free supply to the wash rack.

- highest possible safety within the pipework system by crevice free Neumo-BioConnect flanges (approved e.g. for use of caustic or acetic detergents)
- completely self-draining, vertically installed Circulation pump in 3A2 standard; max. 5.5 kW
- regulated tank heating by means of electric heating or steam heat exchanger in pharmaceutical design ($Ra \leq 0.8 \mu m$)
- pneumatically driven diaphragm valves

Washing system

In consideration of the sensitive washing goods and the high demands on the degree of washing to be achieved, special attention was paid to the coordination of washing solution pressure and through flow volume distribution between external and internal cleaning.

- External cleaning via rotating wash arms at the top and bottom, including optional permanent rotation monitoring
- The internal cleaning of hollow bodies (e.g. drums) takes place via a direct injection system on the wash rack. A perfectly sealing, patented connection coupling with special sealing mechanism ensures a constant pressure, leakage-free supply of the cleaning system and therefore at higher wash nozzle pressure shorter washing times



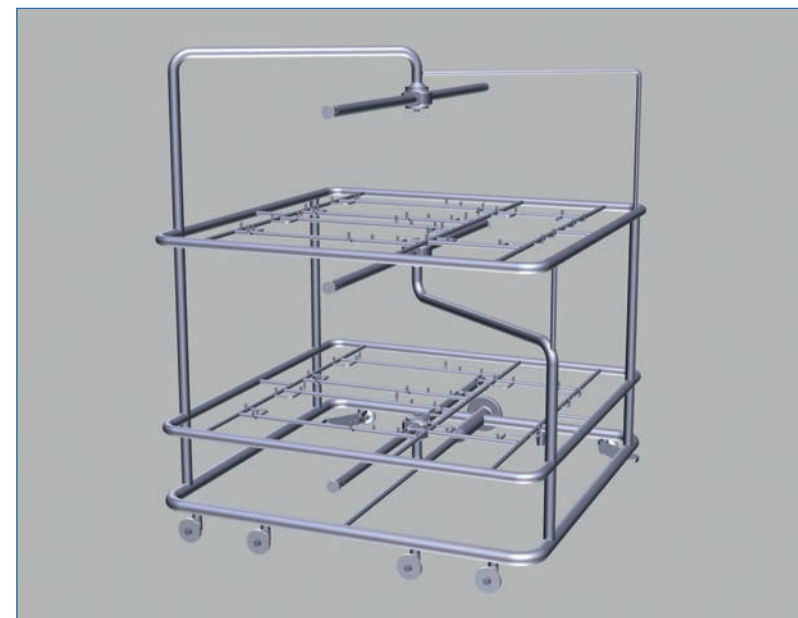
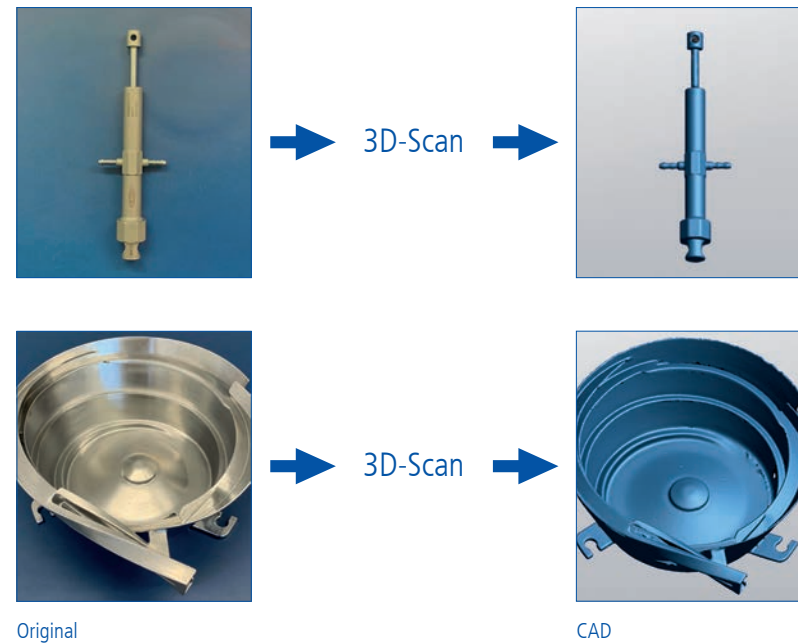
No gaps or dead space: the clever wash chamber design with rounded corners prevents deposits and soiling.

The Heart of the washing process – The Wash Rack

A perfect cleaning result is the result of a reliable washing system, a validated washing process and the correct positioning of the items to be washed on the rack. In many cases, the analysis of the flow of goods and the design of the rack takes more time, than the selection of the washer. Belimed Life Science supports you in creating an optimal design of the rack, so that your washing goods are efficiently and reproducibly clean.

For the perfect design the rack Belimed Life Science adheres to the principles of "Quality by Design". We consistently use 3D models of the wash items so we can use the available space on the rack as efficiently as possible and position the wash items optimally for washing. If these models are not yet available, we measure the wash items on site using the latest 3D scanner technology.

For production release, you will receive the CAD drawings with the exact position of the items to be washed. This enables you to create clear loading SOPs very easily.



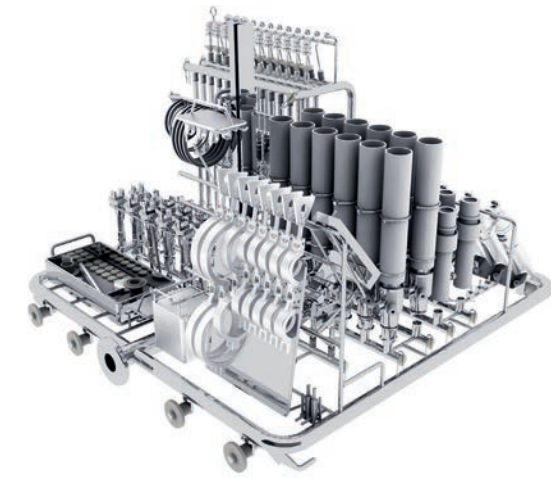
Display of a wash rack

Belimed Life Science Exchange Systems – Space-saving storage for flexible wash item loading

Defined positions of the wash items are required for reproducible washing. For this purpose, a lot of special holders are attached to the rack, whereby flexibility is often lost. In addition, such racks require a lot of storage space in controlled areas when not in use.

Belimed Life Science offers the ideal solution with its Exchange systems:

- defined positions for each wash item on compact Exchange system racks.
- identical water consumption for each Exchange system allows to validate the loads in different combinations
- only one basic system, the universal base can be stored in a space-saving manner
- High flexibility for changing washing goods



Each Exchange system is inserted into the universal rack system with a few simple steps and can also be loaded in advance. This saves time and at the same time prevents unnecessary mistakes from being made. An internal O-ring seal ensures loss-free transfer of the washing liquid to the attached nozzles.

Belimed Prevent™ – because caution is better than leniency

Belimed Prevent Services™ offer a comprehensive portfolio of services covering preventive maintenance, operational services and life cycle management. These services are designed to improve the performance of your Belimed Life Science equipment, reduce downtime and improve the performance of your Belimed Life Science PH washer.

The main advantages

✓ Comprehensive service packages

Belimed Prevent Services™ offers a comprehensive portfolio of services covering preventive maintenance, operational services and life cycle management. These services are designed to improve the performance of your machine, reduce downtime and create real value throughout the entire life cycle of your machine – allowing you to focus on your core business.

✓ Total Cost of Ownership

One of our main goals at Belimed Life Science is to support our customers throughout the entire life cycle of their equipment and to promote the benefits of technology and total cost of ownership (TCO). To measure the performance of equipment and reduce operational and financial risks, customers of Belimed Life Science are more and more interested in long-term service contracts nowadays.

✓ A global network of experts

Our worldwide service network of regional subsidiaries and authorized partners ensures that our trained and certified service technicians react quickly to your requirements and provide spare parts at your location. In addition, our global support team is available to assist you with technical questions – whenever and wherever necessary.



Retrofit packages – always up to date

For existing units a retrofit can be more reasonable than a replacement of a new machine. By replacing obsolete or discontinued components with new, modern technological developments, existing machines can be brought up to date again.

Belimed Life Science offers its customers a wide range of modernization and retrofit measures to optimize functionality and efficiency while reducing the risk of interruptions or downtimes.

We make sure that your machines and systems are always up-to-date throughout their entire service life.

We are familiar with the high demands of pharmaceutical production. We are specialized in finding suitable solutions for these conditions.

Comprehensive services for modernization and conversion measures

- We coordinate the retrofit scope with you
- We check existing control and automation systems
- We develop a meaningful overall concept
- We make an offer
- We process the URS in close coordination with you
- We implement the conversion and commissioning of the machine
- We manage the project with experienced project managers
- We parameterize and optimize the entire system
- We adapt the machine documentation
- We create and manage the necessary change control

Maintenance packages

Belimed Life Science has developed a range of flexible service plans to keep your equipment running. From preventive maintenance and repair work to comprehensive all-inclusive packages.

Lifecycle Services

Extended warranty contracts ensure cost transparency for Belimed Life Science machines over longer periods (2-10 years). In addition, our retrofit packages prevent the equipment from becoming obsolete and avoid expensive downtimes.

Operating services

Consultancy services to help optimise equipment performance and ensure compliance with specifications and latest regulatory requirements is guaranteed.

Design and options

Main features
Wash chamber and piping in stainless steel (AISI 316L)
Complete machine Swiss Engineered
Hygienic design of the complete system both inside and outside the washroom
Self-draining chamber with rounded corners
Surfaces and piping with gradients to avoid stagnant water
Strict adherence to the 3D rule in the design
No unnecessary internals in the chamber to avoid cross-contamination
Patented coupling to the rack for a quick and safe coupling connection
Use of established and reliable components
Pneumatic process valves for process control
Neumo BioConnect® flange connection
Self-draining pump in hygienic design
Inflatable door seals for reliable tightness
Removable front panels in AISI 304 version, resistant to cleaning agents
Compliant with the following guidelines: cGMP, GAMP5, ISPE Baseline Guide, PDA reports
Validation Master Plan (VMP) according to the GAMP5 V-Model

Process and automation features
Fully configurable recipes
Monitoring of the temperature during washing and drying
Software according to IEC 1131, user-friendly 15" HMI with industrial PC
Intuitive operation via touch screen and multi-touch function
Display of the remaining runtime
Batch report output via network printers
Logging of alarms and messages
Sensor calibration
B-Informed Status display of the cycle
Comprehensive software documentation
Paperless batch documentation

Door versions	
1-door	2-doors

Wash chamber position	
Chamber right	Chamber left

Heating	
Washing tank and drying electrically	Wash tank electric, drying with steam
Wash tank with steam drying electrically	washing tank and drying with steam

Electric	
400 V/50 Hz	480 V/60 Hz/UL 508

Surfaces in contact with the product	
Ra < 0.8 µm	Ra < 0.6 µm
Chamber and piping passivated	Chamber and piping electropolished

Process additives	
Direct fresh water rinsing	Direct fresh water rinsing with pulsation
Separate internal and external washing	Program for thermosensitive products
Compressed air blow-out	Sluice program

Control	
Siemens PLC and IPC	Rockwell Allen Bradley PLC and IPC
Interface to MES/SCADA system	Potential-free contact
External control cabinet	Uninterruptible Power Supply (UPS)
Active Directory for B-Touch	Time synchronization via NTP server
Extension HMI on the clean side	Expansion of the recipe memory
Meets the technical requirements for operation according to 21 CFR part 11	

Design and options

Building technology	
Floor trough with drainage	Floor pan with leakage sensor
Dosing via ring pipe	Control of external valve
Transition piece for building piping	Cooling and condensation of exhaust air
Drain funnel for sampling	Exhaust air scoop
Cooling of the waste water	Pre-shut-off valve various media
Bio Seal / Gastight partition wall	Gas-tight additional cladding of the machine
Exhaust air flap	Acoustic alarm signal
Service room lighting	Socket in the service room

Process options	
Frequency controlled pump	Diaphragm dosing pump
Conductivity measurement for pure rinsing	Suction lance for degassing dosing agents
Flow sensor for dosing	Pipe Insulation
Additional suction lance	Conductivity measurement Dosing
Sanitizing the branch line	Inline TOC measurement



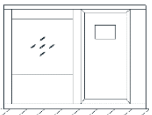


GMP options	
cGMP and ASME BPE compliant design <ul style="list-style-type: none"> Hygienic process piping Aseptic valves 	cGMP compliant documentation <ul style="list-style-type: none"> Risk analysis Functional specifications Hardware specifications 3.1 Certificate according to DIN EN 10204 Welding documentation Etc.
Valve position monitoring	H14 Hepa filter for drying unit
Sampling valve on washing tank	Sampling valve as membrane valve
Rotation monitoring of wash arms	Rotation monitoring of the rack
Polymers and elastomers certified to USP Class VI	Single wire labeling
Component labeling	

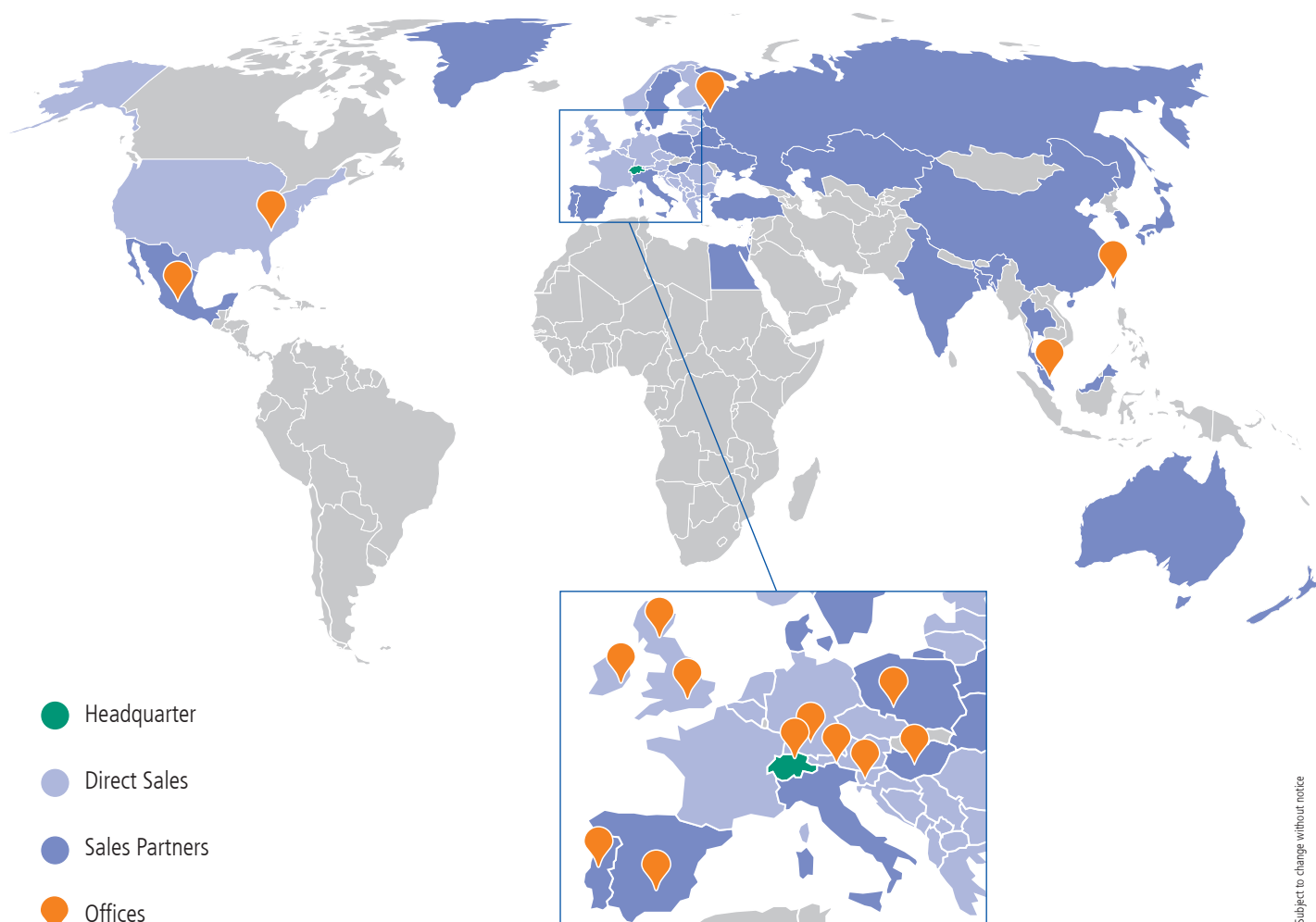
Accessories	
Transfer carriage	Loading trolley
rack for washing goods one floor	rack for washing goods two floors
Creation of the 3D models of the washing goods	rack special design

Qualification	
FAT incl. pre-qualification	SAT
Riboflavin test during FAT	Riboflavin test during the SAT

Warranty and maintenance	
Maintenance contract Belimed Prevent ECO	Maintenance contract Belimed Prevent Standard
Maintenance contract Belimed Prevent Premium	Extended warranty

Dimensions

	Model	Door opening	Usable chamber Size (mm)	External dimensions (mm)	External dimensions without front cabinet- (mm)	System height with open doors (mm)	Loading height (mm)	Base height- (mm)
	PH 820.2	vertical	H: 670 W: 610 D: 750	H: 2.080 W: 1.500 D: 1.125	H: 2.080 W: 1.500 D: 1.020	2.360	800	100
	PH 820.2H	vertical	H: 1.100 W: 610 D: 750	H: 2.510 W: 1.500 D: 1.125	H: 2.510 W: 1.500 D: 1.020	3.220	800	100
	PH 840.2	horizontal	H: 990 W: 830 D: 830	H: 2.080 W: 2.300 D: 1.425	H: 2.080 W: 2.300 D: 1.320	—	800	100
	PH 860.2	horizontal	H: 1.200 W: 830 D: 1.250	H: 2.340 W: 2.300 D: 1.845	H: 2.340 W: 2.300 D: 1.740	—	800	100
	PH 860.2L	horizontal	H: 1.200 W: 830 D: 1.500	H: 2.340 W: 2.300 D: 2.095	H: 2.340 W: 2.300 D: 1.990	—	800	100



Subject to change without notice

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