

Process Vessels

High-quality components and systems for your processes.

Introduction

Established in Slovenia in 1989, Ipros started out developing production plants for the upper echelon of pharmaceutical and other process industries. Today Ipros supplies full-service solutions for plant engineering and construction, as well as automation and installation, with a constantly increasing market share.

Ipros provides its customers with development, implementation, and continuing service from a single source.

All vessels are made out of stainless steel and can be supplied as stand-alone equipment or as automated process units delivered as fully-functional modules installed on-site that include: agitators, homogenisers, metering and regulating technology, control units, valves and pipe connections. Options for hazardous environments are also available.

Our products are in accordance with the Pressure Equipment Directive, and optionally acc. to ATEX, the European directive for systems operating in potentially explosive environments.



ipros[®]

Four groups

- Mobile and fixed vessels or double jacketed vessels for the preparation of suspensions and solutions; volumes up to 700 l.
- Complex mixing vessels for the production of gels, creams, pastes, ointments; volumes from 50 to 2 000 l.
- Reactor vessels for the production of various pharmaceutical products; volumes from 1 000 to 10 000 l.
- Containers and buffer vessels; volumes from 2 l to 20 000 l.

Technical range

- Internal surface quality up to $Ra \leq 0,2\mu m$ grinded, mechanically or electro-polished (surfaces may also be pickled or passivated)
- Steel types regularly used: 1.4404, 1.4435, 1.4541, 1.4571, 1.4539, 1.4547, 2.4605, 2.4610
- Pressure: -1/+10bar depending on customer's requirements
- Temperature: -20° C/200° C (SIP up to 130° C)
- Cleaning options: CIP, SIP
- Single, double, and triple-wall design – heated/cooled, insulated

Standards, guidelines, quality control, documentation, testing...

- cGMP/FDA
- Quality plan and materials tracing
- Non-destructive testing
- Weld seam documentation
- Qualification (IQ/OQ)
- Quality Management System according to DIN EN ISO 9001
- Our quality management system ensures the full traceability of all materials used including the provision of certificates.
- FAT
- SAT
- Riboflavin test
- Heating/cooling test
- Surface roughness measurement
- Design code EN13445 or AD2000

Mobile and fixed mixing vessels for solution and suspension preparation

Vertical cylindrical vessels designed as mobile units. Each vessel is designed individually, according to the customer's requirements, applied technology, and the process itself.

We manufacture vessels for the use under atmospheric pressure and pressurised vessels in the pressure range from -1 to 10bar.



Vessels can be equipped with cooling and heating elements, they can be non-insulated or insulated with insulating material and an insulating jacket (made of stainless steel AISI 304 or other materials) with integrated agitator and other equipment based on order specifications.

These mixing vessels can be mobile as well (on wheels up to 500l and/or with forklift supports for larger capacities).

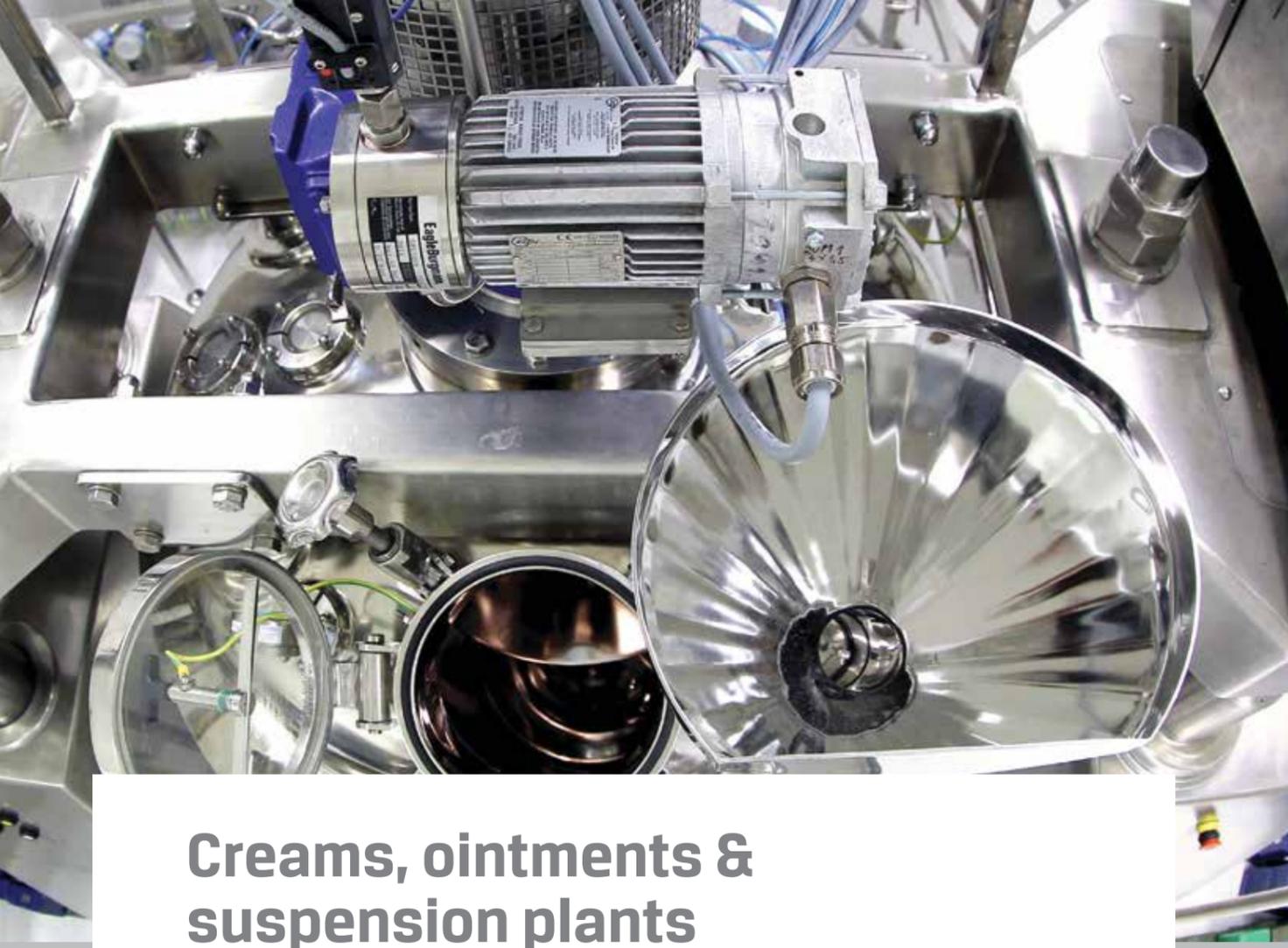
All types of process vessels can be made in ATEX compliant executions.

Applications

- fermenter
- reactors
- bioreactors
- agitator vessels
- preparation vessels
- transport vessels

All our mixing vessels can be connected to various automated or non-automated process systems.





Creams, ointments & suspension plants

Whether or not your process requires sterile conditions, powder and liquid ingredients must be introduced under contained conditions or you simply need a high quality performing mixing & homogenising system under vacuum.

Our designs allow configuring of mixing & homogenising equipment, ranging from vacuum processing to processing under the most stringent sterile and toxic conditions. Various building blocks for CIP and SIP can be chosen to complete the solution to suit your needs.

A wide choice of mixing tools, high-speed dissolvers, and homogenisers with various FDA sealing concepts are available.

Applications

Liquids & semi-solids production for Pharma, Ophthalmics, Cosmetics, Bio, Food, Chemicals.

The counter rotating gear box integrates various functions – mixing, homogenising, cleaning, sterilisation, and drying – into one single validated piece of equipment. This Ipros design can achieve the highest performing CIP/SIP system cleaning and sterilisation results on the market for the mixing and homogenising system.

Designed for high-pressure applications, it has all amenities for efficient Cleaning and Sterilisation in Place. It can also be designed for vacuum processing with easy to use cleaning and sanitisation functions.

Executions, features and options:

- Validated high speed mixing
- Homogenisers/dispersers
- CIP/SIP/drying system
- Vacuum/pressure/N2
- Vacuum foam detector
- Cooling mechanical seals
- Electrics country specific regulations
- Operator panel & software
- ATEX compliant executions

Specifications

- 30 – 1000 litres capacity
- stainless steel GMP machine frame
- motorised lifting pillar
- GMP motor & utility housings
- integrated cleanable & sterilisable energy connections



Reactors and syrup preparation vessels and vessel systems

Syrup and suspensions are typically produced under the same high-quality conditions as applied for sterile processes. Production plants must adhere to strict technical and regulatory requirements; the current GMP guidelines must be taken into consideration as well as the national and international applicable standards.

A consistent plant concept with reliable detail solutions is an indispensable foundation for achieving repeatable high product quality. If these prerequisites have been fulfilled through a high-performance process plant, safe and reliable production is guaranteed.



Production of syrup and suspensions

syrup → semi-sterile production
suspensions → semi-sterile or sterile production

Essential characteristics

- design free of dead-leg areas
- complete drainability
- completely suitable for in-line CIP and SIP (cleaning/sterilisation in place)
- sampling
- diaphragm valve technology
- homogeniser in the circuit or starter vessel
- ATEX compliant execution





Holding vessels, containers and buffer vessels

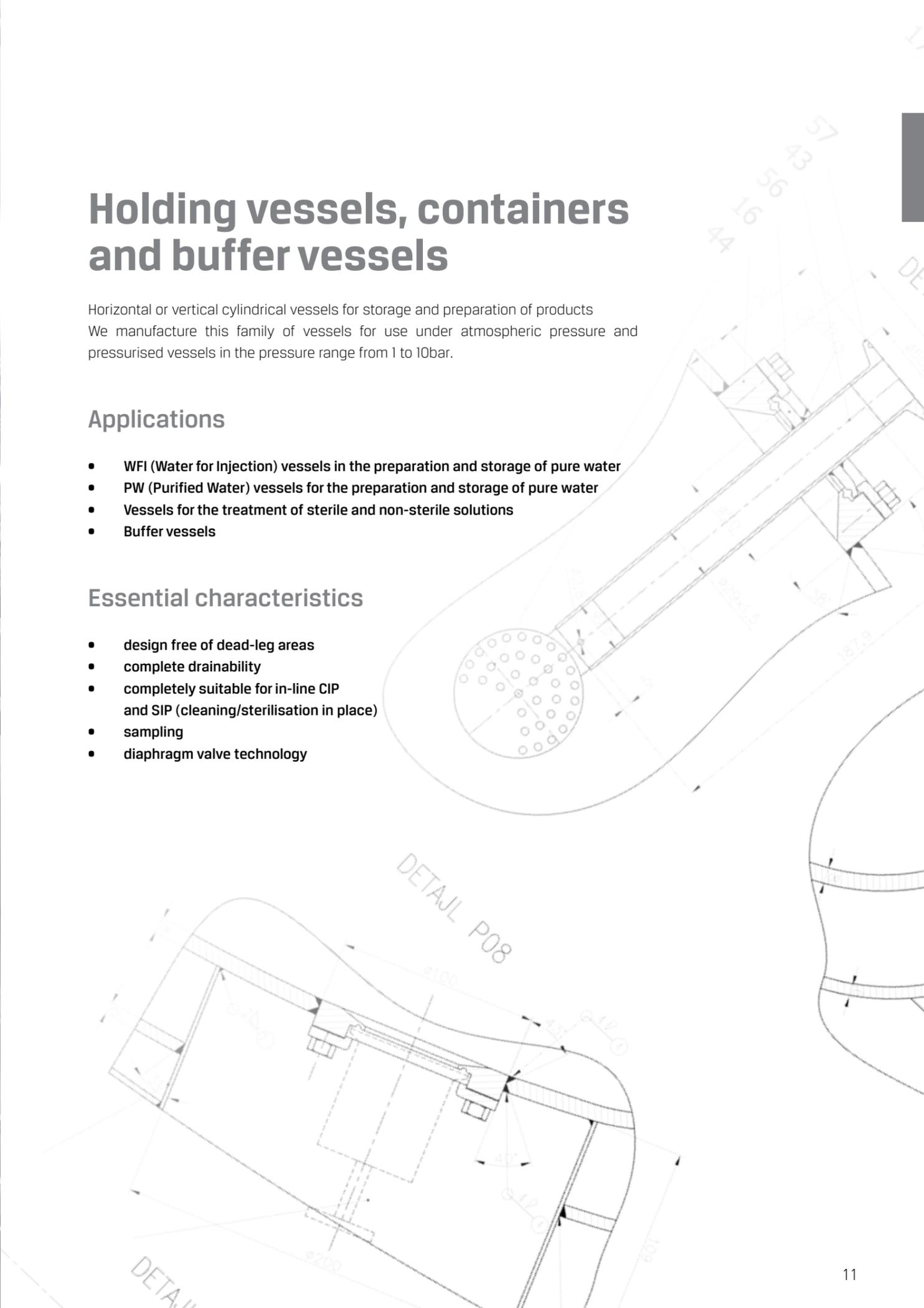
Horizontal or vertical cylindrical vessels for storage and preparation of products
We manufacture this family of vessels for use under atmospheric pressure and pressurised vessels in the pressure range from 1 to 10bar.

Applications

- WFI (Water for Injection) vessels in the preparation and storage of pure water
- PW (Purified Water) vessels for the preparation and storage of pure water
- Vessels for the treatment of sterile and non-sterile solutions
- Buffer vessels

Essential characteristics

- design free of dead-leg areas
- complete drainability
- completely suitable for in-line CIP and SIP (cleaning/sterilisation in place)
- sampling
- diaphragm valve technology



Integration of process vessels / complementary process systems

Preparation and dosing

Our systems optimise these operations, which are vital to a final solid- or liquid-form pharmaceutical process. We provide a range of manual and automated preparation and dosing equipment, creating systems designed to optimise the dosing of ingredients.



CIP / SIP

An essential part of high-quality production is an integrated CIP/SIP system. Ipros provides efficient cleaning and sterilisation concepts adapted to consumer's actual demands and for timely supply of the correct cleaning media to the points-of-use. From mobile and independent cleaning systems up to diverse CIP satellites fed with conditioned cleaning solutions, the range of customized solutions for your process plant is large.



Mixing, heating, and cooling

Temperature control and agitation during the process are crucial for achieving a successful and repeatable outcome. Ipros ensures that the temperature of products in the vessel can be controlled within narrow limits ($\pm 0.5^\circ\text{C}$) to avoid product variation during production.

This high degree of temperature control throughout production processes and product homogeneity is achieved using the latest heat exchanger technology and careful agitation. Precise instrumentation measures all the key parameters of pH, O₂, temperature, agitator speed, and weight throughout processing.



Storage and distribution of GMP media

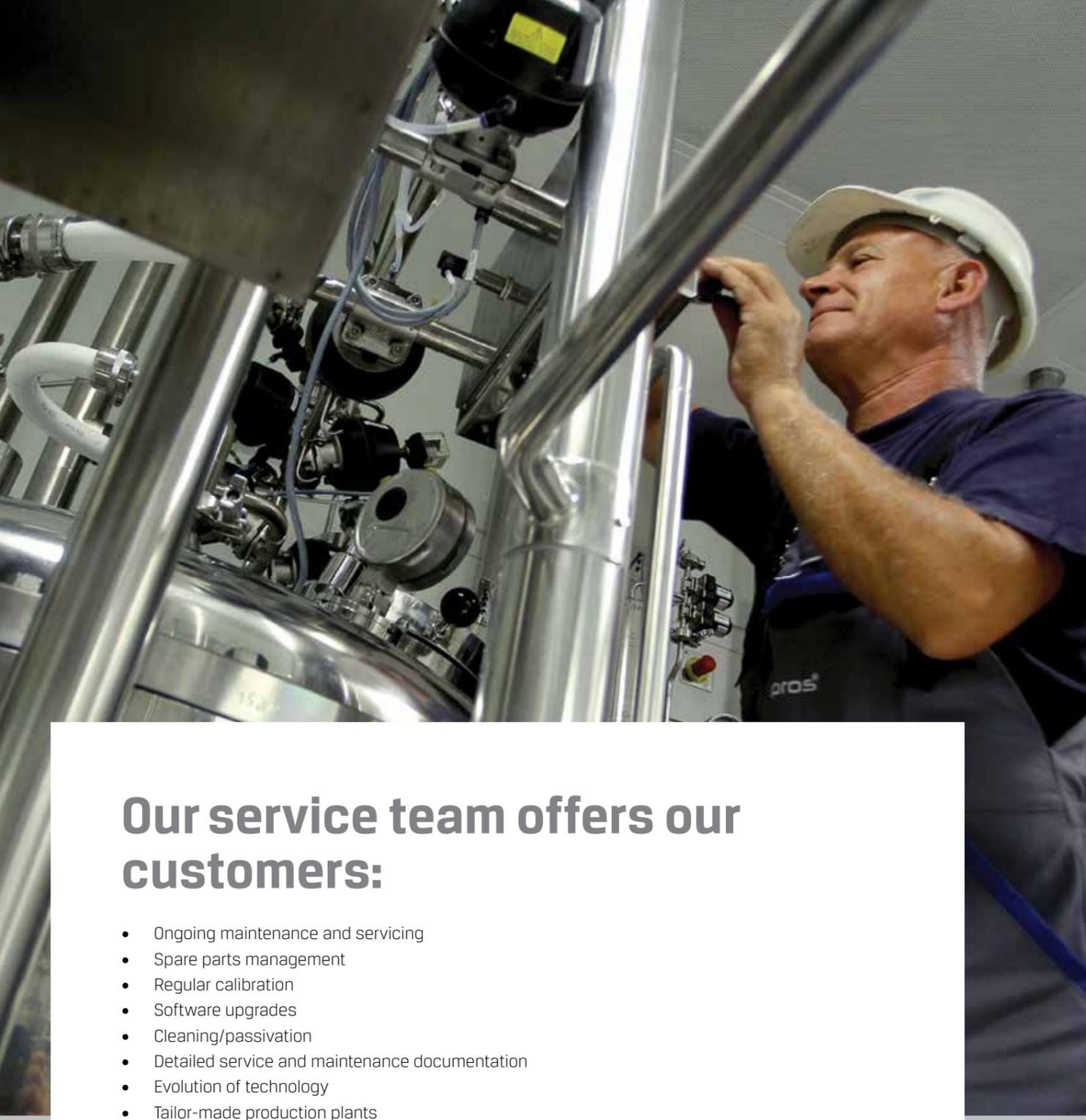
We design, install, commission, and qualify/validate the operation, performance, and maintenance of the storage and distribution system, to ensure reliable, consistent production of media of required quality, in order to prevent recontamination after treatment.



Design, documentation, validation - complete engineering

The design of all the above-mentioned processes, the preparation of: basic and detailed designs, specifications of material and labour, URS, 3D modelling, construction, detailed drawings for manufacture, 'as built' design/projects, technical documentation, validation documentation, validation execution.

Preparation and execution of projects and equipment according to ATEX. Automation of all mentioned above including electrical connections, design documentation, technical documentation, and validation documentation and execution.



Our service team offers our customers:

- Ongoing maintenance and servicing
- Spare parts management
- Regular calibration
- Software upgrades
- Cleaning/passivation
- Detailed service and maintenance documentation
- Evolution of technology
- Tailor-made production plants

As a technology supplier, we stand by our customers as partners in the biotechnological and pharmaceutical industries. We realize integrated system solutions for liquids in sterile and aseptic processes.

The increasingly more exacting requirements for modern production plants require solutions with a high degree of innovation, safety, and quality. All modular skids we manufacture are subjected to a static and dynamic FAT with ultra-pure media (ultra-pure steam, PW and WFI) before delivery.

Ipros's highly qualified and experienced specialists and efficient workflow management guarantee the timely and consistent implementation of customer requirements.

We are trusted by the following companies, among others:

- **Hospira, HR** – preparation and storage of GMP media and of sterile solutions, process mixing jacketed vessels for the preparation of sterile solutions with WIP
- **Sandoz (Lek), SLO** – preparation and storage of GMP media and of sterile solutions, process vessels for the preparation of sterile solutions, several WIP systems and CIP systems
- **Sandoz, PL, RO** – preparation and storage of GMP media and of non-sterile solutions for coating of tablets (acc. ATEX), process mixing jacketed vessels for non-sterile solutions preparation, several WIP systems
- **Krka, SLO** – preparation and storage of GMP media and of non-sterile solutions, process vessels for preparation of sterile solutions, installations (acc. to ATEX), manufacture and installation of a process mixing vessel with peripheral systems (vacuum system, H/C systems, inertisation, lifting, turning...) for the preparation of gels, ointments, creams, pastes... (acc. to ATEX)
- **Polfarma (Medana), PL** – complex process vessel for the preparation of non-sterile products with a mixing system, vacuuming system and a H/C system
- **Sanofi (Zentiva), RO** – process vessels for the preparation of solutions for coating of tablets
- **Teva (Pliva), HR** – preparation and storage of GMP media and of sterile solutions, process mixing jacketed vessels for the preparation of sterile solutions, WIP, process vessels for the purpose of chemical synthesis
- **Jadran Galenski Laboratorij, HR** – preparation of sterile solutions
- **Replekfarm, MAK** – process system for the preparation, storage and dosing of syrups with the H/C system and WIP
- **Medical Intertade (Yasenka), HR** – system for the preparation, storage and dosing of syrups with the H/C system and WIP



SLOVENIA
Ipros d.o.o.

Cesta v Gorice 30
1000 Ljubljana
Slovenija

Boris Dersek
T: +386 1 200 26 20
F: +386 1 423 18 24
E: boris.dersek@ipros.si
www.ipros.si



CROATIA
Ipros – representative office CRO

Milanovačka 14
10090 Zagreb
Republika Hrvatska

Vjekoslav Piljek
T: +385 1 3483 114
F: +385 98 356 349
E: vjekoslav.piljek@ipros-hr.com
www.ipros.si



MACEDONIA
ECOTIP Ltd.

ul.Orce Nikolov 190-3/5
1000 Skopje
Macedonia

T: +389 (2) 3176 920; 3176 907
F: +389 (2) 3177 206
E: info@ecotip.com.mk
www.ecotip.com.mk



SERBIA
Ipros – representative office SRB

Majevička 5
21000 Novi Sad
Srbija

Dragan Brenesel
T/F: +381 21 403 242
M: +381 63 513 819, +386 59 233 162
E: dragan.brenesel@ipros-rs.com
www.ipros.si



ROMANIA
Ipros – representative office RO

Drumul Ciorogarla, 159, sect. 6.
Bucharesti
Romania

Popa Alin Daniel
T/F: +40 21 380 13 30
M: +40 748 06 07 08
E: popa.alin@ipros-ro.com
www.ipros.si



POLAND
Craftech

Ul. Szybowcowa 70/5
54-130 Wrocław
Poland

Łukasz Berbeć
T: +48 71 723 02 94
F: +48 71 723 01 51
M: +48 667 344 377
E: info@craftech.pl
www.craftech.pl