



People. Ideas. Solutions



## Insatech Insacal® and Insacal® mk. II

For in-line or in beaker conductivity calibration from  
UPW/WFI to chemical solution levels.

PHARMA



# Index

## Introduction

Accountability is a key issue in the pharmaceutical and biotech industries. Control of the production process is paramount. Therefore, the timely and reliable calibration of control parameters such as conductivity is a way you can secure your production.

4

## How It Works: Insatech Insacal®

Introduce risk-free calibration of your in-line conductivity sensors with Insatech Insacal – and avoid the disadvantages associated with dismounting the sensors. The Insacal is documented to the degree and requirements of your production process.

6

## Operation: Insatech Insacal®

The Insatech Insacal is easily operated via touch screen and a user-friendly menu structure. Its size and weight mean it can be easily transported to the point of use, minimising calibration hassle and production downtime.

8

## How It Works: Insatech Insacal® mk. II

The Insatech Insacal mk. II is especially made for calibrating and testing low conductivity. 20 years of field experience have gone into its design and intelligent software for the ease and benefit of your calibrations. It also features predefined areas as specified by your requirements.

10

## Operation: Insatech Insacal® mk. II

Choose your way of calibrating: does at-line or in-beaker better fit your needs? By using the Insatech Insacal mk. II you can achieve uncertainty that is four times less than the specification in the USP.

12

## Which Insacal® should I choose?

The instrument you should choose depends on your requirements and factory conditions. Get an overview of the difference and what your options are.

14

## Product specifications

Get an overview of the operating ranges and measuring accuracy of each Insacal.

16

## Service support

Insacals are virtually maintenance-free and only require yearly calibration to ensure reliable measurements. Should you wish, training, service or the support of our skilled technicians is only a phone call away.

17

## What we do

Insatech is highly experienced in delivering applications with high standards to the pharma, biotech and food industries. Our DANAK-accredited laboratory supports our customers with the traceable calibrations of its measuring equipment.

18



# Conductivity calibration matters

**Accountability is a key issue in the pharmaceutical and biotech industries, because these are products that end up in the human body. Manufacturers are therefore expected to maintain strict control of the production process, where calibration and conductivity are important control parameters.**

## **What is conductivity and why do we measure it?**

Conductivity is a measure of how many ions are present in water. Drinking water often contain many ions, which is not a problem when being drunk, but when it is used in pharmaceutical products that end up in the human body, the ions can harm us. For this reason, a great deal of legislation specifies the quantity of ions that may be present in water used for pharmaceutical products.

To avoid harming the body, the pharma and biotech industries use ultra-pure water (UPW) and water for injection (WFI) in their production. To ensure that the water is within the specification, the ion concentration is measured using conductivity. This is achieved by measuring how much current can pass through the water. The smaller the current, the fewer ions are present in the water. Conductivity is therefore a typical control parameter.

## **Why do we need to calibrate?**

Instruments are used to measure the quantity of ions in the water and are therefore used to control the quality of the water, but how can we ensure that the instrument measures correctly? This is where calibration comes in. Since the precision of the instrument can drift during use, we must ensure that the conductivity sensor measures correctly – this is what calibration does.

Inaccurate measurements can have costly consequences, such as entire batches having to be discarded, production stops, etc. Faulty products can also hurt your product or brand name.

## **Two ways to calibrate conductivity**

There are two fundamentally different ways to perform conductivity calibrations. One is by using a standard, which is a liquid solution with a known conductivity. The other is by comparison with a reference instrument such as the Insatech Insacal described in this brochure.

When choosing your methodology, you need to take several things into consideration.

## **Using standards**

Standards require that you have calibration expertise in order to properly perform the calibration, since multiple factors – e.g. temperature and contamination – will influence results and, more specifically, your calibration uncertainty. To conduct the calibration, the sensor you want to test must be removed from the process. This in itself introduces a variety of problems in terms of closing down parts of the process, re-sanitising the loop, risk of contamination, etc. But most importantly, it can be very hard to recreate the environment and install conditions in the laboratory, and if the conditions vary too much, this can render the calibration useless. Calibrating by way of standards can therefore be difficult and costly work.

## **Using reference equipment**

Instead, we recommend the use of reference equipment such as the Insatech Insacal. One of the main reasons for using reference equipment is that it can be used at-line in order to calibrate in-line instruments. This means that you do not need to remove the unit under test (UUT) when you calibrate and therefore do not have to re-sanitise the loop after the calibration. Furthermore, the calibrator is placed in the same environment as the UUT, which means you do not have to worry about recreating environment and install conditions. Overall, performing good calibrations with the Insacal is easy and requires very little training. In addition, carrying out calibrations of multiple loops become very cost effective, especially when done at-line or using an Insatech T9 Calibration Tank.



# How it works: Insatech Insacal®



**Conductivity calibration is a basic requirement in pharma and biotech production. Instead of settling for varying uncertainty, why not reduce it to a minimum and save time and money? It can be done quickly and easily with the Insatech Insacal®.**

## Risk-free calibration of in-line sensors

Traditionally, when calibrating a conductivity sensor you would need to dismount it from the production line and then calibrate it with a standard solution either at-line or in a calibration laboratory. This operation has a number of disadvantages, as it interrupts production and introduces some uncertainties and risks. Furthermore, you risk contamination of your production line. Our solution is the Insatech Insacal.

When calibrating conductivity, the calibration method must represent the way the equipment is used on site. In some cases, the calibration set-up must be an exact copy of the field installation; if not, the sensors must be calibrated in a closed loop. With the Insatech Insacal you can validate and calibrate sensors in line without removing them from production, eliminating contamination risks, uncertainties and interruption of production. Essentially the calibration works by comparing the UUT with the reference.

## Made for the pharmaceutical industry

The Insatech Insacal has been developed for the pharmaceutical industry. The casing is made of AISI 304 stainless steel. It is dust-tight and cleanable for clean room use according to industry standards. The Insatech Insacal is equipped with a flow fitting for the sensor to avoid the influence of the surroundings when used for in-situ calibrations. All wetted parts can be cleaned in place (CIP) and steamed in place (SIP).

When the Insatech Insacal is delivered, it is tested, calibrated and ready to use. It can be used in all non-hazardous areas on site or in the laboratory and can be used to calibrate conductivity measurements from UPW or WFI up to chemical solution levels.

## Calibration of Insacal

The Insatech Insacal is calibrated as follows: the cell constant of the reference is determined in a primary standard solution with the best possible traceability and uncertainty. The standard solution comes from Danish Fundamental Metrology (DFM), the national metrology institute of Denmark, which deals with conductivity.

The transmitter/indicator is calibrated electrically throughout the remainder of the operating range. The temperature measurement is calibrated as a loop system (sensor and indicator). We can, however, incorporate other user-specific designs as you prefer.



## Insatech T9 Calibration Tank

*The T9 Calibration Tank for the Insatech Insacal can help you perform loop calibration of your sensor. Your sensor is easily connected to the tank and the Insatech Insacal. The tank holds up to 9 litres of calibration fluid, which a pump circulates through both the unit under test and the Insatech Insacal, making it effortless to calibrate your sensors.*



*Insatech Insacal® for fast and easy validation  
of in-line conductivity sensors.*

# Operation: Insatech Insacal®



**Insatech Insacal® is your way to a fast and reliable calibration. Its user-friendly touch design enables your calibration technicians to conduct efficient calibrations you can trust.**

## Fast and easy calibration

The Insatech Insacal is very easy to use – just carry it to the instrument you need to calibrate, connect it to a power supply and place the electrode in either the flow fitting, beaker or a calibration tank, depending on your preferred method of calibration.

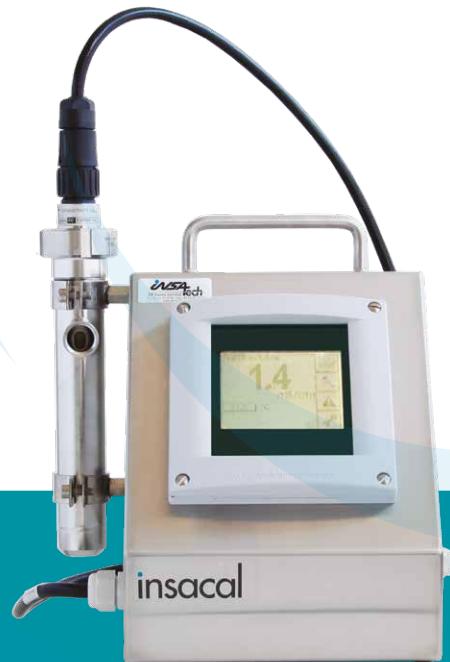
To calibrate in-line equipment, you connect the flow fitting to a test valve near the UUT, place the electrode in the flow fitting and wait for the measurement to stabilise. Then you compare the measurements of the Insacal to the UUT. For beaker calibration, place the electrodes of both the Insacal and the UUT in a stirred vessel/container, wait for stable measurements and then do the comparison. This set-up is only recommended when you need to calibrate values above 5 µS/cm. With the Insatech T9 Calibration Tank, you can place several UUTs in the tank and use the build in circulation pump of the T9 to flow the calibration solution through the flow fitting of the Insacal, and furthermore be able to calibrate values in the lowest range.

## Intuitive touch screen operation

The Insatech Insacal is operated via a touch screen. The interface is very intuitive and you can easily navigate between the different menus. At the start screen the reference, temperature and conductivity are presented on the display. To add security, the transmitter settings can be password-protected to avoid unintentional changes of settings or the cell constant. The software supports multiple languages.

## Easily transported and no permanent installation required

The Insatech Insacal is handy and weighs less than 4 kg. The sturdy design together with the solid handle makes it easy to transport to the point of use and well-suited for calibrations anywhere on site. Since the Insatech Insacal can be inserted into a beaker or flow fitting, no permanent installation is required.



*Insatech Insacal® is used worldwide in the pharma industry, and our calibration engineers use it for on-site calibrations.*



# How it works: Insatech Insacal® mk. II



**Is low conductivity particularly important to you? The Insatech Insacal® mk. II is a calibrator specialised in this area. It can be predefined for your factory conditions, helping you reduce any uncertainty to a bare minimum.**

The Insatech Insacal mk. II has evolved from the Insatech Insacal and is specifically for UPW/WFI applications up to 1000 µS/cm, which means it is suited to both the biotech and pharmaceutical industries. The new features, design and software are based on knowledge we have gathered from our customers and calibration technicians over the past 20 years.

The Insatech Insacal mk. II is designed especially for low range conductivity, which is particularly difficult to calibrate. When you are conducting a calibration the Insatech Insacal mk. II acts as your reference; i.e. you compare the value of the unit under test (UUT) with the Insatech Insacal mk. II, either directly at the process loop or in a beaker set-up.

The mk. II is calibrated at UPW and 1.3 µS/cm as standard, but other points can be chosen. The cell constant is determined at 100 µS/cm.

## At-line conductivity calibration

One of the strengths of the Insatech Insacal mk. II is that it enables you to verify calibrations directly where your process takes place. This is done by attaching the mk. II to an existing test valve in the loop where your conductivity equipment is installed. The advantage of using at-line calibration is that the calibration runs in process conditions, which are impossible to recreate in the laboratory. Furthermore, you avoid contaminating the process loop when you remove and re-install the UUT.

## Temperature compensation at user-specified ranges

The Insatech Insacal mk. II features temperature compensation, which is used at specific ranges to show what the conductivity would be if measured at 25 °C. The Insacal mk. II comes with two predefined ranges – 0 to 50 °C and 50 to 90 °C – but you can specify your

own ranges with a two-to-five point linearization. This means that if your process works only within a specific temperature range (for example, 30 to 60 °C), you can improve the temperature compensation accuracy by using a five-point linearization within that range.

Note that the Insacal mk. II can show both compensated and non-compensated measurements simultaneously.

## Verify conductivity points electrically

The Insatech Insacal mk. II features optional resistors that can be used to verify a specific conductivity point. This gives you added security at certain measuring points.

Use the feature by plugging in a resistor that matches the specific conductivity you want to measure – for example, 1.3 µS/cm. When you place the electrode in the test chamber, the electrode is tested electrically against the resistor. This means that you can verify your measurement regularly between calibrations and ensure that you measure as accurately as possible. For example, the feature can be used to ensure that an alarm limit is measured as accurately as possible.

Resistors can be delivered for any point between 0.055 and 1000 µS/cm.

## Measurement uncertainty reduced to a minimum

The above electrical verification feature is also why the Insacal mk. II can achieve an uncertainty that is four times less than specified in the USP at 100 µS/cm. When the mk. II passes the electrical test, the only uncertainty left is from the 100 µS/cm calibration in the laboratory at Insatech. When you achieve an uncertainty that is four times less than the UUT, the uncertainty of the reference instrument is so low compared to the UUT that it becomes negligible.





*Insatech Insacal® mk. II is a low conductivity calibrator  
for UPW applications.*

# Operation: Insatech Insacal® mk. II



**Calibrating your conductivity sensors can be challenging, especially at low conductivity, but whether you need in-line or beaker calibration, the Insatech Insacal® mk. II will provide you with fast and reliable results.**

Like the Insacal, the Insatech Insacal mk. II is operated via an intuitive touch screen, and calibration can be carried out in two ways: directly in the process or in a beaker. Both ways use comparison calibration between the Insacal mk. II and the UUT.

## In-process calibration via flow fitting

The at-line comparison calibration is performed by connecting the Insacal mk. II to a pre-existing test valve. The media can then flow through the Insacal mk. II flow fitting, and once the readings have stabilised, you can compare the measurements of the UUT with the Insacal mk. II.

The main advantage of at-line calibration is that you calibrate in process conditions, which are very hard if not impossible to recreate in a laboratory. Furthermore, the closed system protects against CO<sub>2</sub> dissolving into the water and changing the conductivity during calibration. Lastly, you do not have to remove the instrument from the production line, thereby avoiding contamination risks as well as the need for redocumentation, which is both time-consuming and costly.

## Point calibration via calibration tank

The unit can also be used in a calibration tank setup. In this case the UUT electrode is placed in the calibration tank during the calibration while the calibration solution is circulated through the flow fitting of the Insacal mk. II.

When calibration is performed via the Insatech T9, it is entirely up to the operator how the calibration is carried out. The calibration can be performed at multiple points using a saline solution and adjusting the solution with water or salt. This enables you to calibrate your instruments at the points most suited to your process, while being able to control the conditions yourself.

Be advised that in practice this set-up can be difficult to stabilise under 2 µS/cm due to contamination by calibration tank, sensors and air. For the best result with a beaker under 2 µS/cm we recommend using the T9 Calibration Tank with a lid and resin bed in order to minimise CO<sub>2</sub> contamination and remove contaminants.



*With the Insatech Insacal® mk. II  
you can achieve an uncertainty that is  
four times less than specified in the USP.*



# Which Insacal® should I choose?



To help you choose the Insacal® model that is best suited to your calibration needs, please read the recommendations below.

## When to choose the Insacal®

You should choose the Insacal if you need the broad calibration range from 0.055 µS/cm to 240 mS/cm or just the higher range.

The broad range may be preferable in the pharma and biotech industries if you wish to calibrate instruments for both the ultra-low range UPW/WFI and higher range applications like washing. However, the Insacal does not support an uncertainty four times less than specified in the US Pharmacopeia\*.

The higher ranges may be preferred in the chemical and general industries.

## When to choose the Insacal® mk. II

You should choose the Insacal mk. II if you need to calibrate in the ultra-low conductivity range from 0.055 to 1000 µS/cm.

The mk. II is made especially for conductivity calibration in UPW and WFI. Therefore the mk. II is used mainly in the pharma and biotech industries. The system also makes it possible to achieve an uncertainty four times less than specified in the US Pharmacopeia\* at 100 µS/cm.

You should also choose the Insacal mk. II if you want to have greater flexibility to optimise the adjustment of the conductivity measurement.

\* Ph. eur.: Cell constant must be known within 2% and/or system within 3%.

USP: Cell constant must be known within 2%.



### Calibration tank

The Insatech T9 Calibration Tank for the Insatech Insacal can help you perform loop calibration of your sensor. Your sensor is easily connected to the tank and the Insatech Insacal.

The tank holds up to 9 litres of calibration fluid, which a pump circulates through both the unit under test and the Insatech Insacal, making it effortless to calibrate your sensors.



### Transportation and storage case

The optional case fitted for either of the Insatech Insacal products ensures safe transportation and storage of the equipment.

# Product specifications



**What are your factory requirements? Go over the parameters for the Insatech Insacal®'s below to find out which option is best suited to your conditions.**

	<b>Insatech Insacal®</b>	<b>Insatech Insacal® mk. II</b>
<b>Linearisation of temperature measurement</b>	x	x
<b>Built-in electric calibration feature</b>		x
<b>1:4 ratio at 100 µS*</b>		x
<b>Touch screen HMI</b>	x	x
<b>Interface language</b>	Multiple	English
<b>User adaptability</b>	Fixed Yokogawa set-up	Customisable
<b>Electrode</b>	Yokogawa	Hamilton
<b>Conductivity range</b>	<b>Low range:</b> 0.055 to 1000 µS/cm @ 25 °C  <b>High range:</b> 1 to 240 mS/cm @ 25 °C	0.055 to 1000 µS/cm @ 25 °C
<b>Sensor cable length</b>	2 or 5 metres	2 or 5 metres
<b>Cell constant determined</b>	<b>Low range:</b> Standard solution at 100 µS/cm combined with an electrical calibration  <b>High range:</b> Standard solution at 10 mS/cm combined with an electrical calibration	Standard solution at 100 µS/cm and comparison calibration at UPW and 10 µS/cm
<b>Cell constant accredited calibrated to</b>	<b>Low range:</b> 0.34% (by standard solution method)  <b>High range:</b> 0.26% (by standard solution method)	0.34%
<b>Temperature range</b>	Calibrated range 0 to 90 °C ( $\pm 0.5$ °C)	Calibrated range 0 to 50 °C ( $\pm 0.20$ °C) 50 to 90 °C ( $\pm 0.40$ °C)  Customer-specified range of 0 to 90 °C determined by 2 to 5 points
<b>Standard flow fitting</b>	Mini-clamps	Mini-clamps

\*Test Accuracy Ratio for USP645



# Service and support

You have bought an Insacal® product. Now what? All you need to remember is to carry out an annual calibration to ensure continued fast and reliable measurements. Service, support and training are only a phone call away.

## Minimal maintenance

Insatech Insacal products are developed for pharmaceutical use where easy maintenance and cleaning are essential and these can be done according to industry standards. Maintenance is limited to a yearly calibration of the conductivity sensor. Maintenance and recommended spare parts may vary depending on the specifications but will always be described in the delivered documentation.

## Service and support are readily available

We know that the after-sales experience is important to you and your total product experience, which is why we have a well-staffed service department ready to help you if challenges should arise. We perform repairs on location or in our workshop, depending on what is most beneficial in the given situation. Accredited calibration will be performed in our calibration laboratory.

Both Insatech Insacal products are built with standard components so that spare parts are easy to obtain. If you choose a service agreement with us, we will take responsibility for the timely calibration of your instruments.

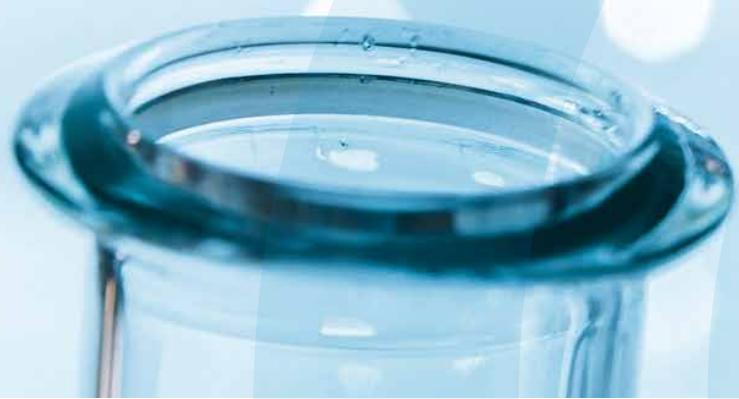
## Training

The ever-increasing complexity of measuring equipment makes proper training invaluable. We can offer equipment and application training at your preferred facility. Furthermore, the training will be targeted towards your various production set-ups, ensuring you get the greatest benefit possible.





# What we do



Over the years Insatech has become a trustworthy and competent partner, supplying technical solutions and providing advice to the process industry. We have great experience with the particular applications and rigorous documentation requirements of our primary markets, the pharma, biotech and food industries. We work according to well-recognised standards – e.g. ISO 17025, FDA, EHEDG and Good Automation Manufacturing Practice (GAMP).



## Insatech calibration laboratory

An important part of the development of Insacal® products, as well as of the after-sales service and support we supply, is our accredited calibration laboratory. To retain our accreditation and CAL reg. no. 484, we are audited by the Danish Accreditation Fund (DANAK) on a yearly basis.

The benefit of using an accredited laboratory is the reduced cost of recalibrations. We supply documented knowledge that will save you time and minimise your expenses with regard to measurement flaws and irregularities.

## One of only a few in the world

We are one of only a few companies in the world that offer accredited calibration of conductivity. The accreditation guarantees that you get traceable documentation proving that your equipment is within specifications and has been evaluated by an independent calibration facility. Using our





laboratory also ensures that your equipment is calibrated to the standards required by the United States Pharmacopeia (USP) or European Pharmacopoeia (EP). We maintain traceability by having our references calibrated by national or international calibration laboratories accredited according to ISO 17025.

At Insatech we develop, produce and sell products in the fields of measurement and calibration. Our products are highly customisable, and we are certain that we can meet your user requirements specification (URS).

#### **Flow Calibration Rig**

The Flow Calibration Rig provides a swift and risk-free way of calibrating flow meters in line. Carrying out the calibration in line eliminates costs from lost production, saves hours on the calibration process and minimises the risk of contamination by active process ingredients (API). As an added bonus, the total test loop is checked, eliminating uncertainties that could occur in the laboratory.

The rig is a plug-and-play solution that can be delivered with traceable DANAK accreditation and accuracy of < 0.3% of the measured value, and which covers a flow range from 5 to 40,000 kg/h. Cleaning can be performed according to industry practice and all wetted parts are CIP-able.

#### **Quantity Calibration Rig**

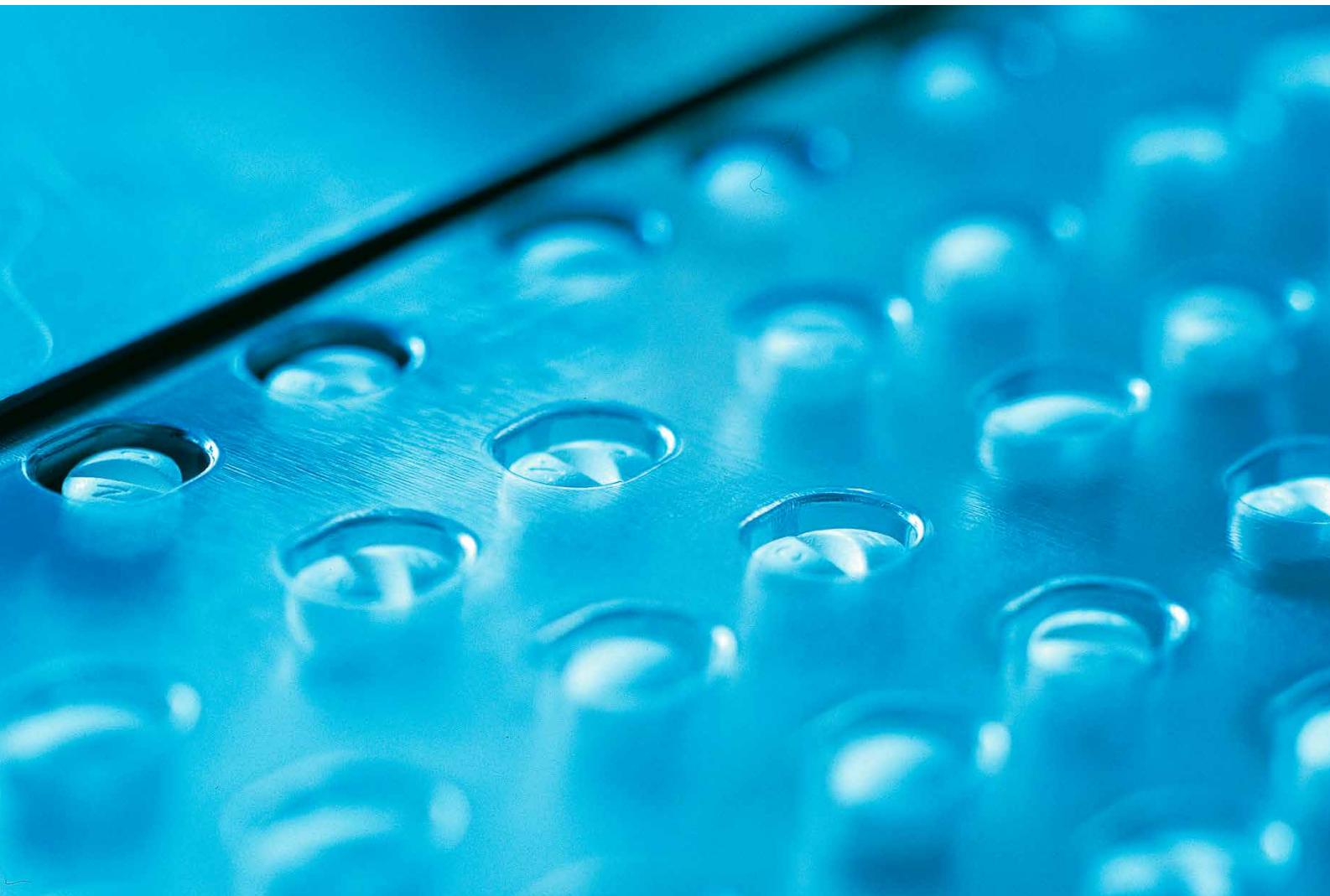
The Quantity Calibration Rig can be used for the calibration of loading cells for level measurement equipment in e.g. production and fermentation tanks by dispersing a pre-defined batch of fluid on the basis of volume or weight. The calibration is highly accurate and stable, and the skewed distribution of calibration points helps target certain flow ranges.

The flow rig can be delivered with a traceable DANAK accreditation and accuracy of < 0.3% of the measured value, and covers a flow range from 5 to 17,000 kg/h. Cleaning can be performed according to industry practice and all wetted parts are CIP-able. The rig can be produced to operate in hazardous areas (ATEX Zone 1).





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*The Insatech Insacals ensure fast and reliable calibration of high and low conductivity sensors.*

## PHARMA

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