



# Application Systems for the Highest Standards

# State-of-the-art primary packaging for decades

Egon Schwab  
**founded**  
Aero Pump



Development  
**COMOD®** System



Development  
preservative-free  
**3K®** System

1976

1979

1988

1992

1993

1997



**First**  
pharmaceutical  
**customer:**  
Hoechst AG  
(Sanofi-Aventis)



Development  
**Emergency Spray**  
for patients with  
cardiovascular  
diseases

Foundation of  
subsidiary **Ursatec** for  
preservative-free systems



# State-of-the-art primary packaging for decades

Company headquarters  
Hochheim  
finished



New administrative  
headquarters  
finished

Market entry  
in field of  
Pulmonary



2001

2006

2009

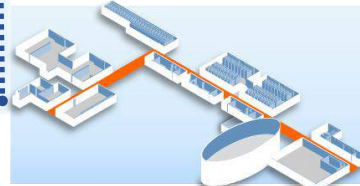
2012



2017

2019

Market launch  
Ophthalmic  
Multidose  
System



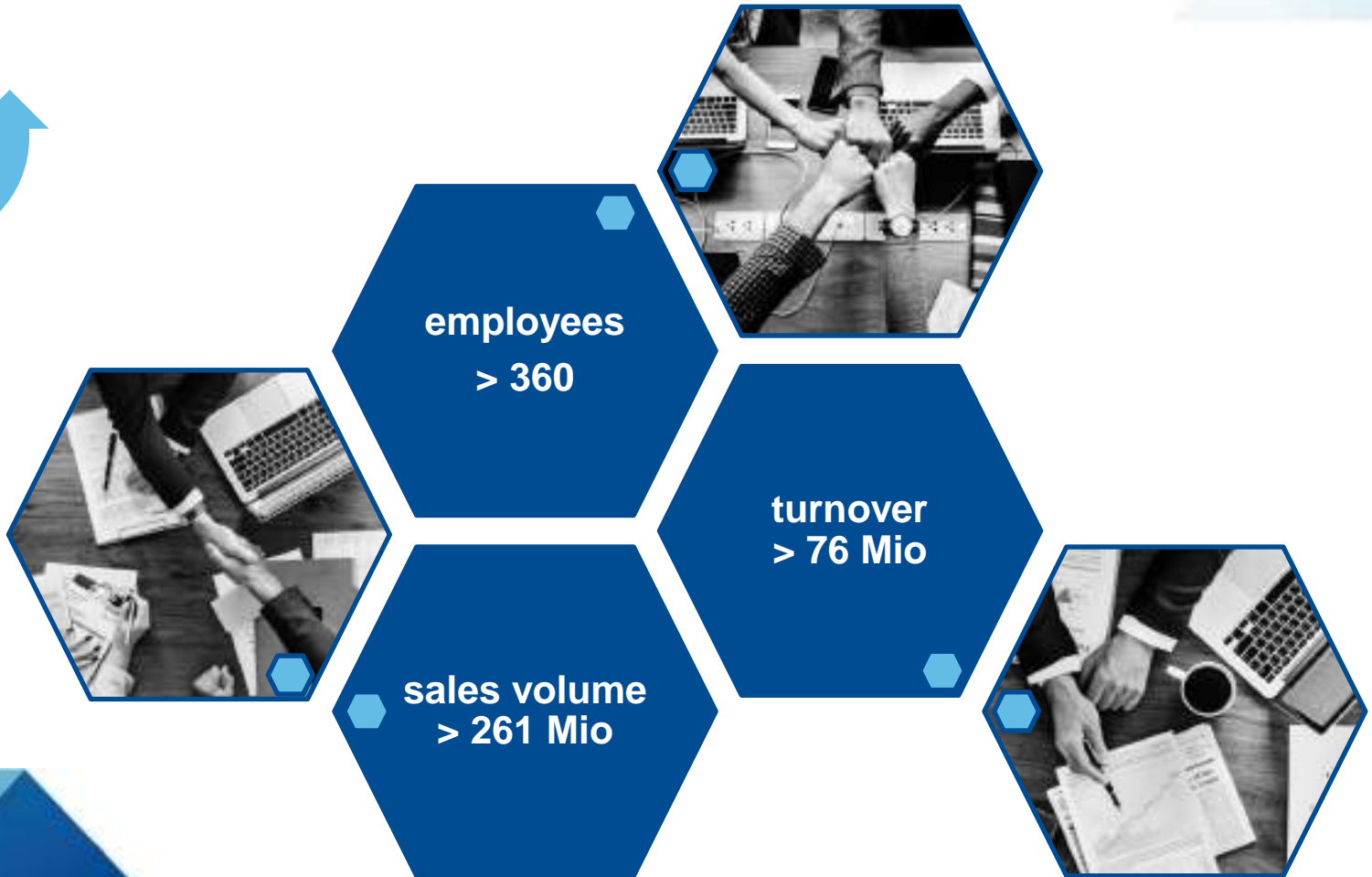
Doubling manufacturing area; **Work-flow-optimization** / automation



Ophthalmic  
Side  
Actuation  
Device

# Economic Growth

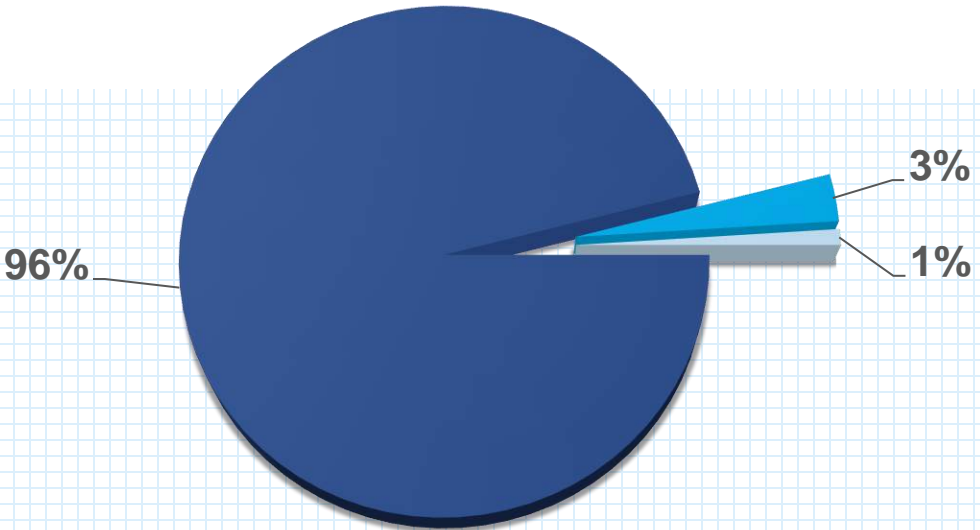
CAGR (5y)  
Ø 4,10 %



Considered year: 2022



# Business Segments



■ Pharma/ Healthcare    ■ Cosmetics    ■ Technical



# Manufacturing

- Revolutionary injection molding concept
- Assembling area 1.750 m<sup>2</sup>
- Manufacturing process according to GMP
- Complete batch traceability
- ISO class 7 manufacturing conditions



# Quality:

## We work according to our customers' standards

### CERTIFIED QUALITY MANAGEMENT



#### Quality

DIN EN ISO  
9001:2015



#### Environment

DIN EN ISO  
14001:2015



#### Energy

DIN EN ISO  
50001:2018



#### Primary packaging for pharma- ceuticals

DIN EN ISO  
15378:2018-4



#### Medical products

DIN EN ISO  
13485



# Portfolio







# Ophthalmic Multidose System





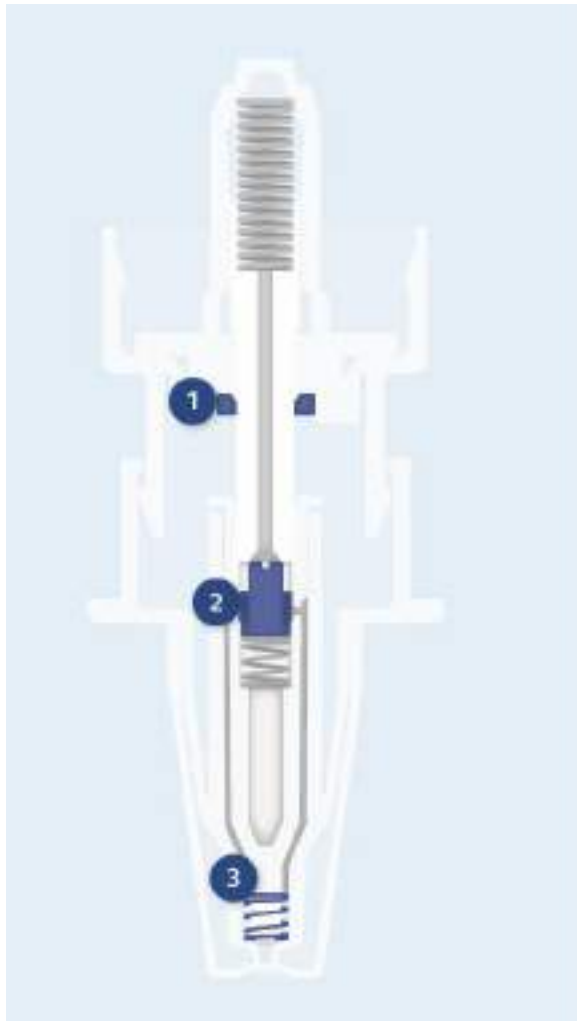
# Ophthalmic Multidose System

- Dosages available: 28 mg, 45 mg
- Customized dosage possible
- Compatible with 5 and 10 ml plastic, tubular or molding glass bottles
- Snap-on closure is safe from inadvertent opening
- Mechanical pump for constant actuation force until completely empty
- Suitable for various formulations and viscosities





# Ophthalmic 3K<sup>®</sup> Technology



## The 3K<sup>®</sup> system with triple protection



1 The filter matrix prevents contaminated air ingress.



2 The valve is protected against reflux and prevents product backflow.



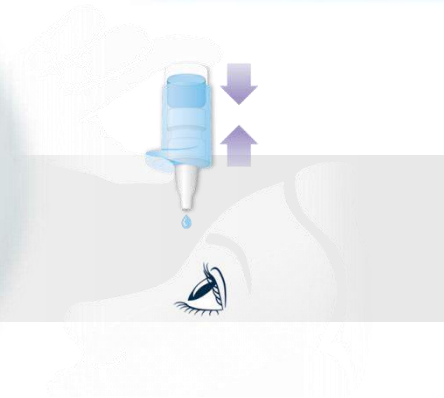
3 A coil with oligodynamic effect in the tip prevents microbiological growth.



# Patient Usability

## ComfortGrip

- Increased patient's safety
- Intuitive and easy to use
- Optimized actuation grip



## SAD

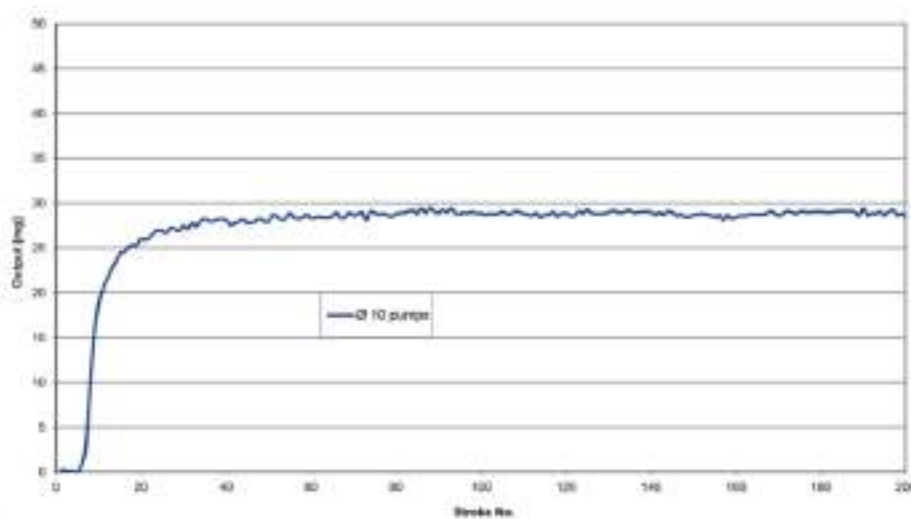
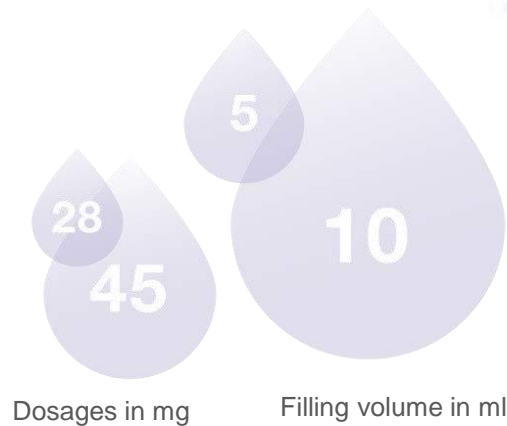
- SideActuationDevice
- Reduced actuation force
- Intuitive and easy handling
- Pump system with accurate dosing



# Metered dose / Documentation

## Metered dose

- Exactly defined drop size
- One drop per actuation



## Documentation

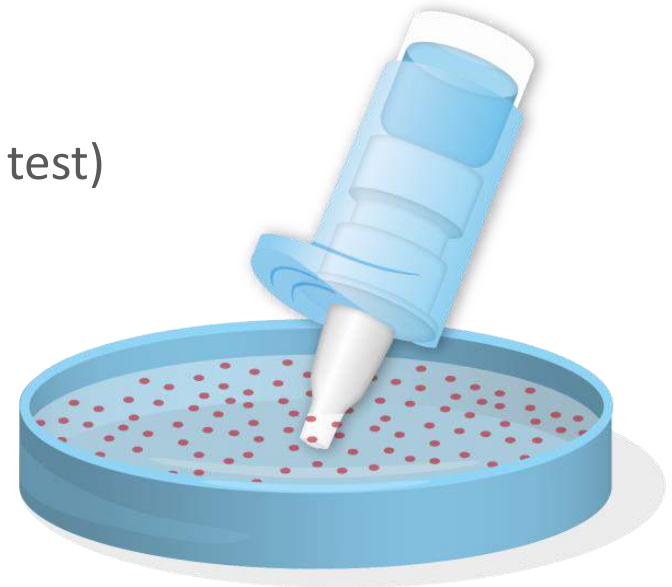
- Drug Master File
- Complete material documentation
- Technical drawings
- Extractables data
- Material data sheets



# Microbiological Challenge Test

## Analyses

- Dynamic Integrity test
  - Oligodynamic effect test
  - In-use stability test
  - Test in contaminated ambient air (aerosol test)
- Test methods according to Ph. Eur 2.6.1  
or USP <51>



Bacteria: e.g. *Pseudomonas aeruginosa*



## FILLING PROCESS



GMP Class A - Clean Room

Ready, filled, microbiological sealed 3K System





# Ophthalmic Sprays

## Lidspray

- Application onto the eye lid (closed eye)
- Product will be dispersed in the eye after blinking

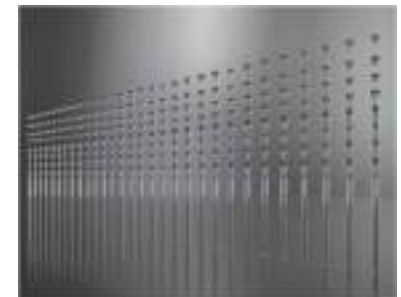


## EyeSprayer

- New technology creating a soft mist onto the opened eye, no blink reflex!
- Droplet size  $>10\mu\text{m}$  (adjustable via different orifice diameters)

## Rayleigh Spray Principle

droplet diameter =  $2x$  jet diameter



# Nasal Application Systems



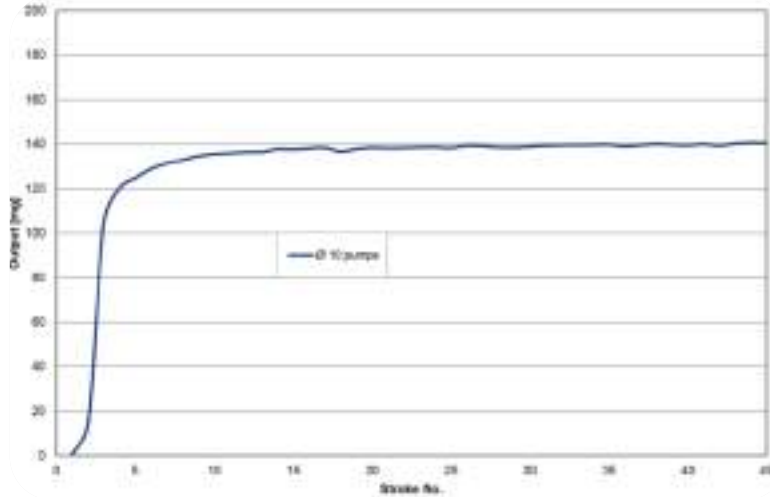
# Adaptable for OTC, Rx and Generics

- Dosages available: 45 to 140 mg
  - Customized dosage possible
  - Compatible with 10, 15, 20 and 30 ml plastic, tubular or molding glass bottles
  - Suitable for diverse formulas and viscosities
  - Pump for preservative-free solutions
- available from partner Ursatec

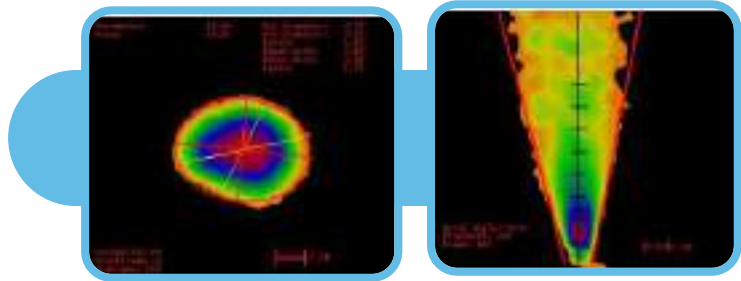


# Precise metered dose

- Exactly defined dosing per actuation
- High dosing accuracy & consistency
- Adjustable spray pattern for individual requirements



- State-of-the-art  
Spray Pattern & Plume Geometry analysis



# Nasal Dropper / AeroLock CR

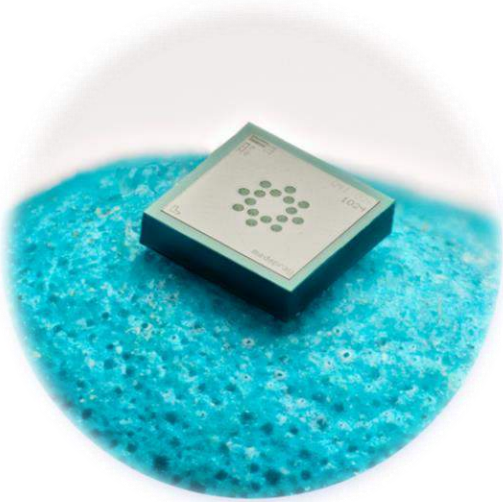


- Defined drop size: 28, 45, 85mg
- Especially suitable for babies & children
- Gentle nasal medication
- Applicable in up-side-down position

- Intuitive push-and-twist system for simple handling
- Function tested according to US 16 CFR § 1700.20 and ISO 8317



# SoftSpray / Luer lock Adapter



- Ultra-fine mist for sensitive nasal applications
- Unique and innovative spraying technology
- Fine spray in metered dose

- Our nasal spray adapter for Luer lock systems
- For applications such as flu vaccines
- Cost-effective readily available solution





# E-Device valiDOSE



- Exoskeleton for conventional pumps
- Digital augmentation sleeve
- Biometric security/ Temper-evidence
- Improved patient adherence







# Pulmonary Application Systems





# Unique inhalation technology for liquid medications

## Ecomyst90

A unique preservative and propellant-free liquid inhaler that delivers an ultra-fine and dosed spray for prescription products aimed at lung conditions such as COPD and asthma.



## SoftBreezer

One of its kind across the world, this preservative and propellant-free liquid spray delivers a dosed ultra-fine spray for gentle application to the mouth, throat, and bronchial area.



# Key Benefits

- No propellants – no CFCs, HFAs or VOCs
- Preservative-free application
- Multidose bottle: 200 doses (5 ml bottle) or 400 doses (10 ml bottle)
- Waste prevention due to Multidose design
- Pocketable size

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➤ Sustainable and Cost-effective solution





# Specification of Soft Mist Inhaler

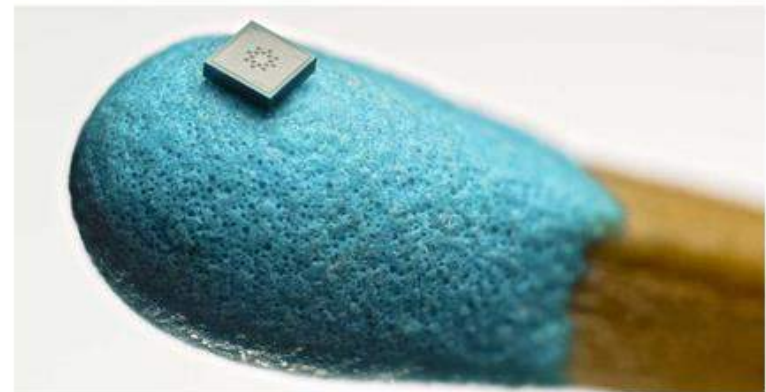
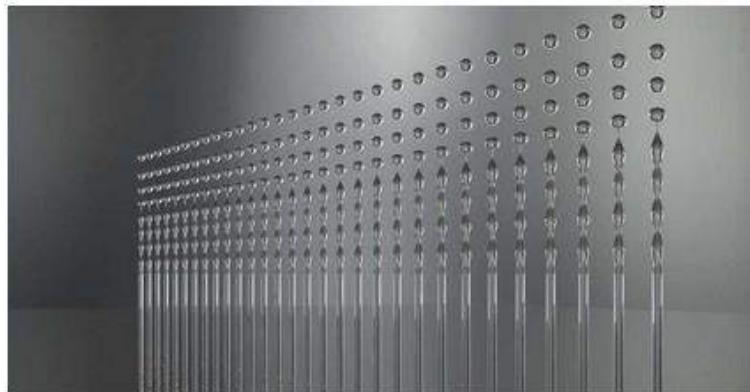
- Metered dose: 25  $\mu$ l
- Emitted dose: > 90% of metered dose
- Lung deposition: about 50 %
- Alveolar dose: approx. 20 – 25 %
- Respiratory resistance at 2 kPa: 20 l/min
- MMAD: 3,5 – 7,0  $\mu$ m (depending on formula)
- Activation time: 2,5 seconds
- Compatible with 5 and 10 ml plastic, tubular or molding glass bottles





# Spray Nozzle Unit (SNU)

The Spray Nozzle Unit (SNU) ensures innovative ultra-fine spray action. The liquid flows through the nozzle in uniform intervals according to the Rayleigh principle, which ensures an ultra-fine and precisely dosed spray mist. This new nanotechnology in the Spray Nozzle Unit is the first of its kind across the world.

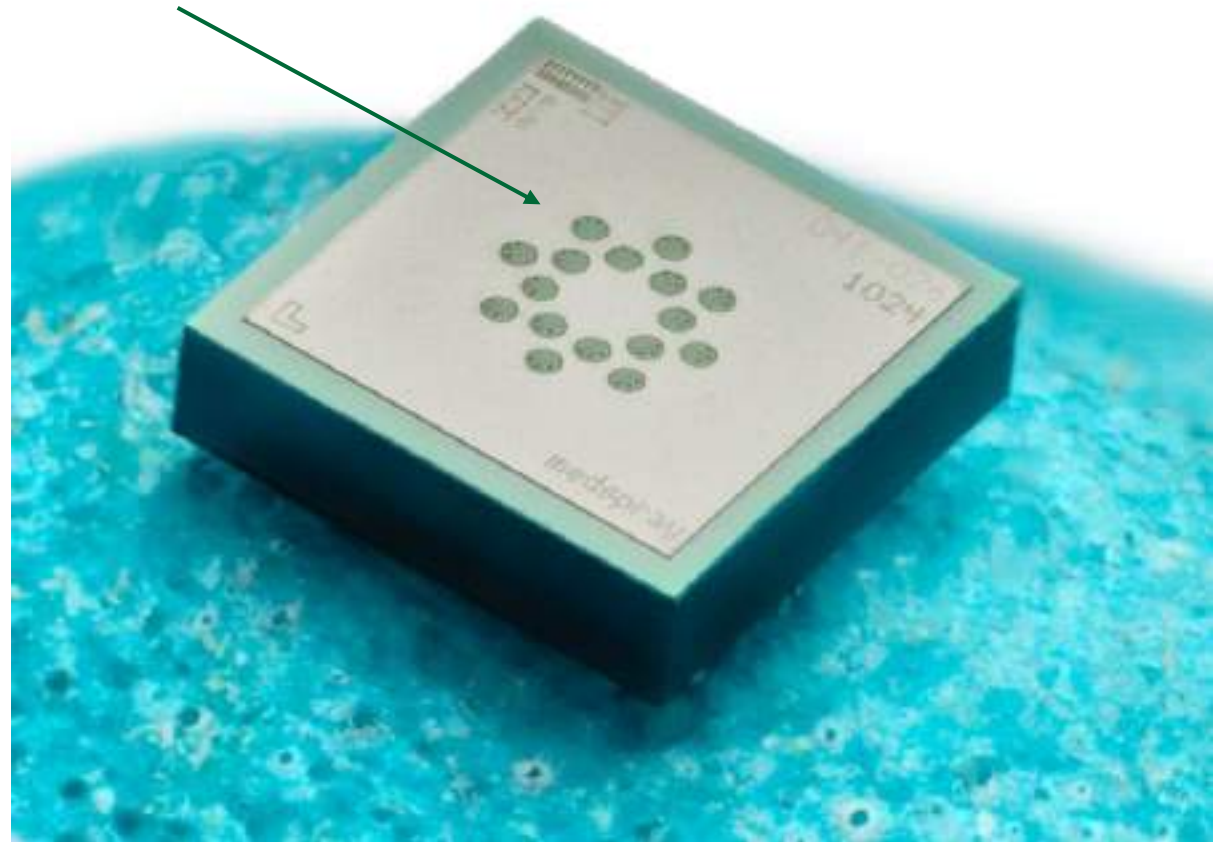






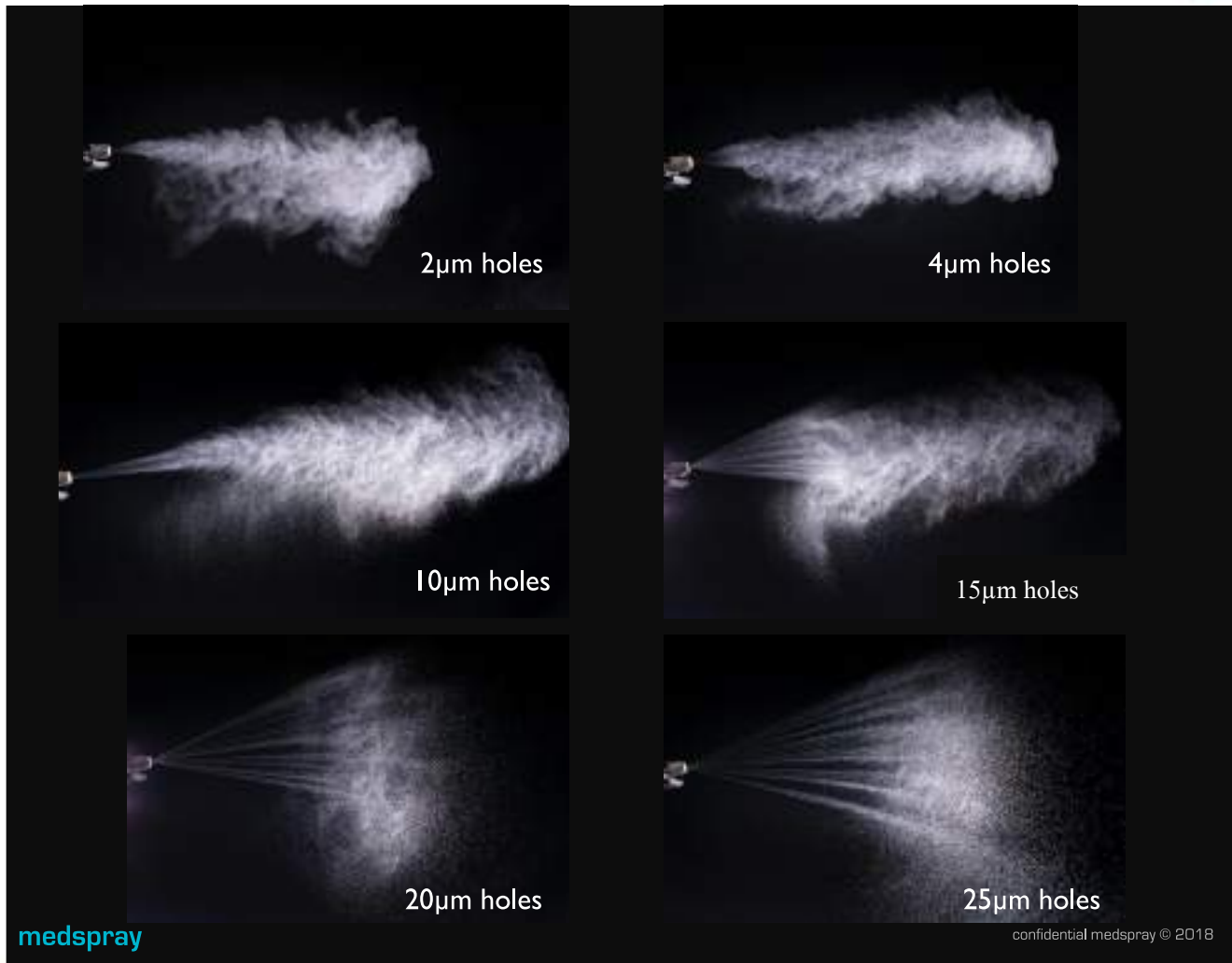
# Spray Nozzle Unit (SNU)

Orifice size adaptable between 1 – 50  $\mu\text{m}$





# Spray Nozzle Unit (SNU)







# Buccal Spray Application





# Adaptable for OTC, Rx and Generics

- Dosages available: 100 to 180 mg
  - Customized dosage possible
  - Compatible with 10, 15, 20, and 30 ml plastic, tubular or molding glass bottles
  - Suitable for diverse formulations and viscosities
  - Adjustable spray pattern for individual requirements
  - Pump for preservative-free solutions
- available from partner Ursatec



#### Snap-on closure

Snap-on closures are safe from inadvertent opening and efficient in processing.



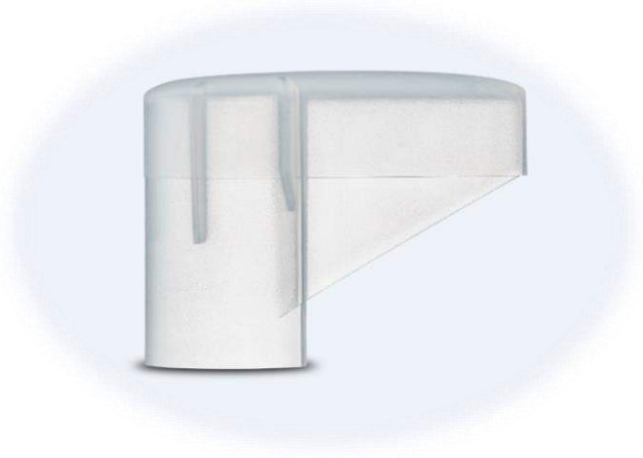
#### Screw-on closures

Simple to open by twisting.



# Mouth Spray / Sublingual Spray

- Examples include acute treatment for cardiovascular disease
- Accurate and reliable dosing
- Fast priming for immediate use



- Protection against nozzle contamination
- Protection against inadvertent activation while on the move
- Available in various colours



# Otological Spray Application





# Ear Spray Adapter

- Dosages available: 65 to 130 mg
  - Customized dosage possible
  - Compatible with 10, 15, 20, and 30 ml plastic, tubular or molding glass bottles
  - Suitable for diverse formulas and viscosities
  - Microbiological seal directly behind the nozzle
  - Pump for preservative-free solutions
- available from partner Ursatec







# Topical Application Systems





# Medical products, cosmetics, and industrial applications

- Dosages available: 45 to 200 mg
  - Customized dosage possible
  - Compatible with 10, 15, 20, 30, and 50 ml plastic, tubular or molding glass bottles
  - Suitable for diverse formulas and viscosities
  - Adjustable spray pattern for individual requirements
  - Pump for preservative-free solutions
- available from partner Ursatec

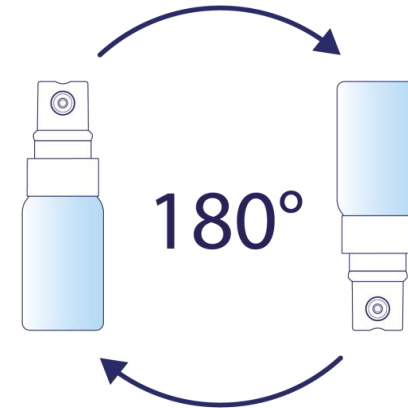




# Solutions for special requirements

## UpSideDown

- Application with the pump upright or upside-down
- Ideal for applications in difficult to reach areas
- 140 mg dosing



## Airless

- 360° applicable
- Closed system – no air ingress
- Supports special patented bag-in-bottle system



# Solutions for special requirements



## Long Nozzle

- For high-viscosity fluids (e.g. oils)
- Unique design
- Exact dose



## CRC Nozzle

- For creams and high-viscosity fluids
- Unique design
- Exact dose



## Ultra-Soft Spray

- For spraying ultra-fine mist in sensitive applications
- Innovative and unique spraying technology
- Fine spray in metered dose

# Support



- ✓ Dosage determination test
- ✓ Droplet size distribution (DSD)
- ✓ Spray Pattern & Plume  
Geometry analysis
- ✓ Actuating force determination
- ✓ Priming and repriming  
behaviour

- ✓ Drug Master Files
- ✓ Complete material  
documentation
- ✓ Technical  
drawings
- ✓ Extractables data
- ✓ Safety data sheets

- ✓ Dynamic Integrity test
- ✓ Aerosol test
- ✓ Oligodynamic effect test
- ✓ In-use stability tests

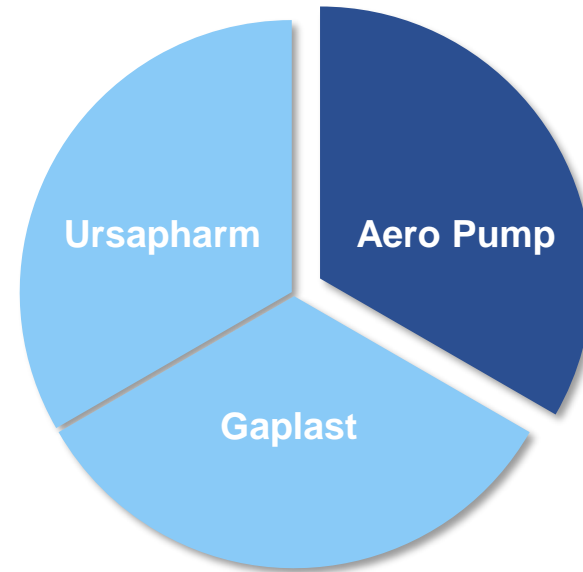
# URSATEC GmbH

## Portfolio

- 3K<sup>®</sup>-Nasal, 3K<sup>®</sup>-Topical
- 3K<sup>®</sup>-Buccal/ Otological
- COMOD<sup>®</sup>-System
- COMFORT<sup>®</sup>-System
- Full-service contract manufacturing

## Partner for Sterilization

- ETO-Sterilization
- Validated process ISO 11135:2007
- According EMEA Guideline



Ownership





Thank you for your interest in our company and products!