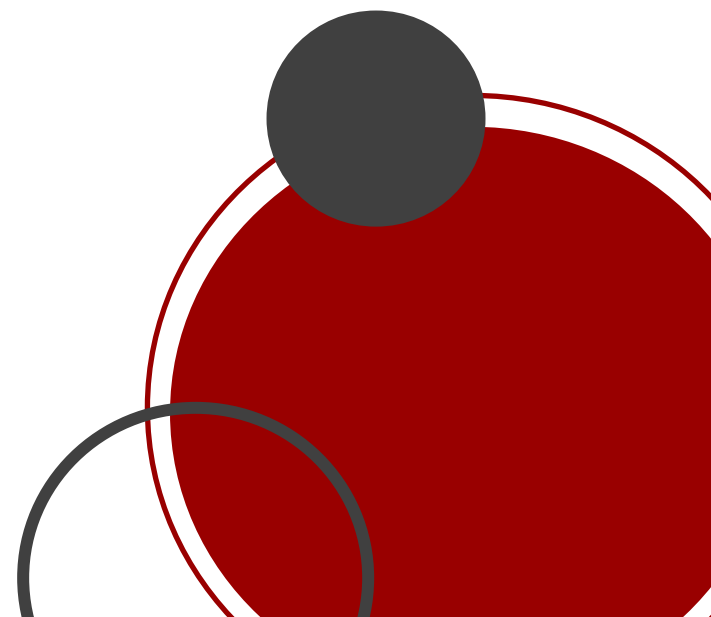


SykonaHaler - The Blister Based Solution!

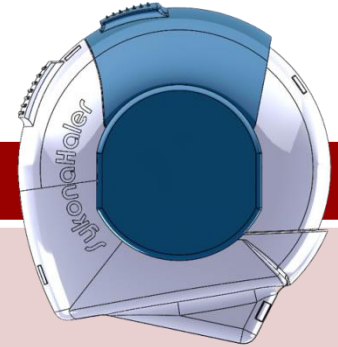


Reference Product – Diskus from Glaxo

- Our Device needs to be equivalent to the Diskus of GSK
- We do not have an infringement in the IP because our key visions are different from the Discus Device.



What Should a Blister MDPI Offer?



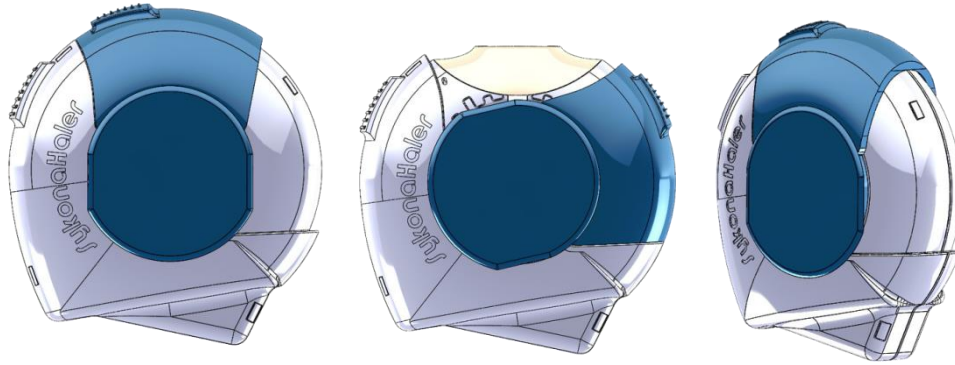
For Patients

- Clear reassurance of dose delivery
- Intuitive handling
- Minimal patient coordination
- Minimal number of handling steps
- Clear reassurance of dose delivery
- Small and portable design
- Full and consistent dose delivery

For Distributors

- Flexible design
- Low production price
- High recommendation rate among patients
- Easy and cost effective assembly
- Easy and cost effective packaging

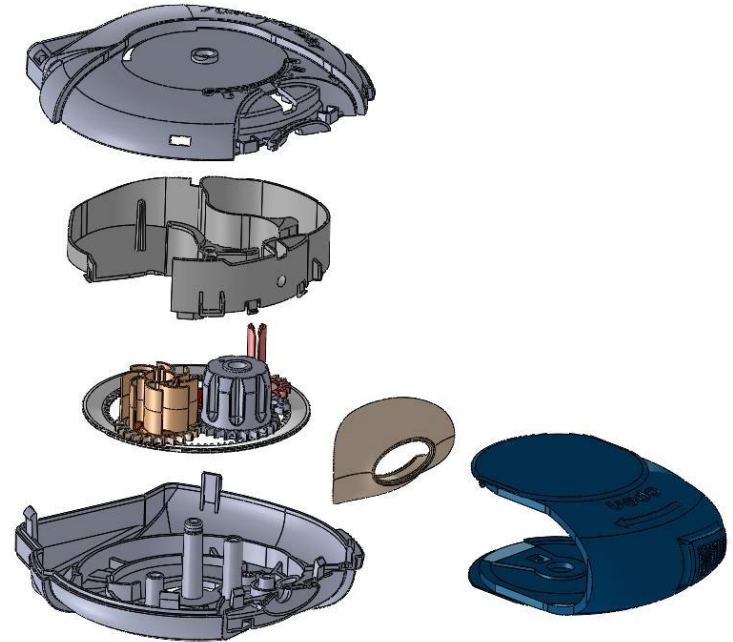
Basic Design Layout of the SykonaHaler



Compact and Simple Design

In designing the SykonaHaler, we have kept in mind all relevant factors for the two main players – producing companies and patients.

We have created a **cheap** and **smart** new MDPI.



SykonaHaler - Advantages

Simple in handling, **reduced number of operation steps** for the end user. **“All in One”** Opening and peeling of the strip when opening the Cover!

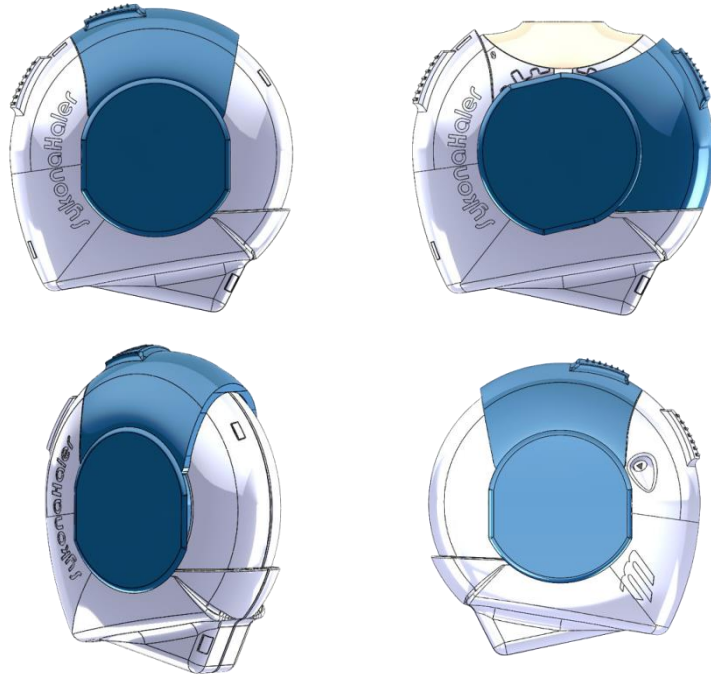
Customized Design - the **OuterCase color can be adapted** to customers needs.

The gearbox contains a **blister strip with 60 filled cavities**.

Manual or automated device assembly possible.

Mematec is a **turn key supplier**

- Device License Contract covers the full supply chain. Device with the required documents, blister strip drawing, foil material specification, moulding tools, assembly equipment for clinical phase 1 -3 and small scale production, plastic parts and assistance in the physical powder formulation and assistance in powder filling.



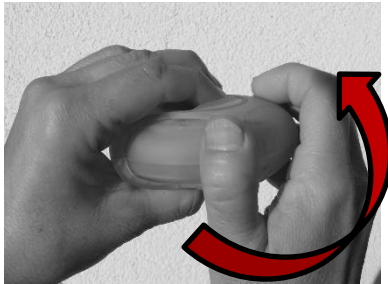
Due to the simple activation, the patient misuse rate is expected to be lower

SykonaHaler – Device Handling

Open the cover

To open the device, hold the body base in one hand and put the thumb of your other hand on the outer case chamber.

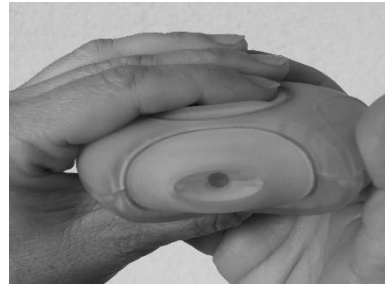
Push your thumb away from you as far as it will go. You will hear a click. This will open a small hole in the mouthpiece.



Prepare substance for use

Hold the device with mouthpiece towards you. The drug is now made available for the user.

Attention! Every time the outer case is pulled back a cavity is opened. The outer case is not to be opened unless there is intend for use, otherwise the substance is wasted.



Inhale substance

Hold device away from mouth, breathe out as far as comfortable.

Do not breathe into the device.

Put the mouthpiece to your lips; breathe in steadily and deeply through the device. Remove device from mouth. Hold your breath for as long as is comfortable (min. 10s). Breathe out slowly.

*Rinse mouth with water and spit it out to prevent thrushes or horse voice.

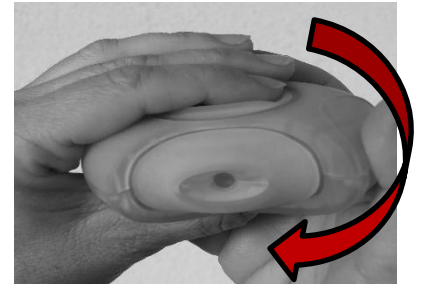


Slide back Cover

To close the device, slide the finger grip of the outer case back towards you, as far as it will go.

You will hear a click. The internal drive wheel gear (lever) will return to its original position and reset.

The device is now ready for use again.

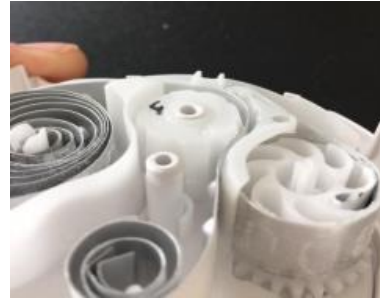


SykonaHaler - USP and Bio Equivalence Data



SykonaHaler Design Features

- Exact positioning of the strip to the mouth piece opening
- 61 cavities for ideal indexing the strip to the final cavity
- 1 Test Pocket to check the correct assembly of the gears and respiratory path
- Lock to prevent re-opening of the device to ensure malfunction
- Automatic indexing of the strip by opening the cover



SykonaHaler – Bio Equivalence Data – Device Resistance

	GSK		
Volumenstrom V	P1	P2 *	P3*
100	5,78	0,87	0,24
90	5,10	0,87	0,24
80	4,49	0,87	0,24
70	3,84	0,87	0,24
60	3,32	0,87	0,24
50	2,74	0,87	0,24
40	2,28	0,87	0,24
30	1,93	0,87	0,24
20	1,63	0,87	0,24

L/min kPa

	SykonaHaler		
Volumenstrom V	P1	P2 *	P3*
100	7,07	0,85	0,24
90	6,20	0,85	0,24
80	5,44	0,85	0,24
70	4,60	0,85	0,24
60	3,93	0,85	0,24
50	3,24	0,85	0,24
40	2,65	0,85	0,24
30	2,13	0,85	0,24
20	1,68	0,85	0,24

* P2 and P3 are required for the Venturi principle.

SykonaHaler: 74 L/min \pm 7,5 % bei 4 kPa

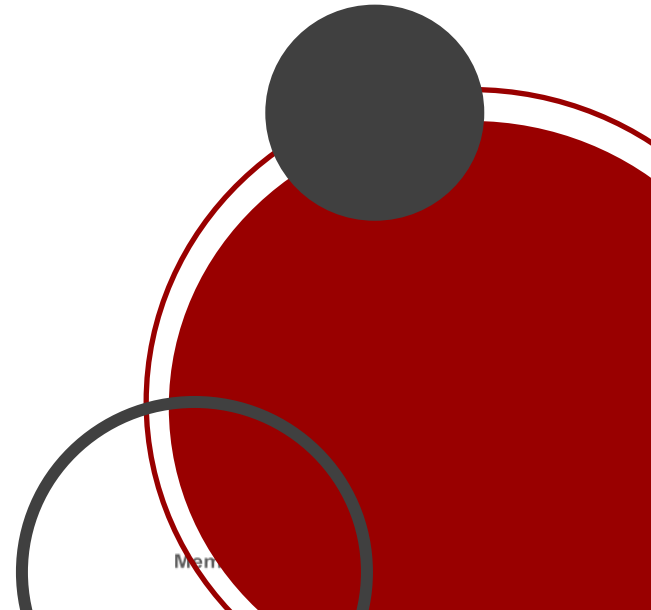
SykonaHaler – Bio Equivalence Data – Salmeterol

Salmeterol	Device 1			
Flow rate @ 4kP	74.6	72.99	74.55	73.78
Shot no	2 to 11	30 to 32	50 to 52	58 to 60
Delivered	46.108	49.130	48.925	44.946
Fine Particle Dose μg	9.220	8.322	7.725	8.398
Fine Particle Fraction %	19.996	16.939	15.790	18.685
MMAD	2.624	2.668	2.570	2.704
GSD	2.352	2.433	2.471	2.534

SykonaHaler – Bio Equivalence Data – Fluticasone

Fluticasone	Device 1			
Flow rate @ 4kP	*74.6	72.99	74.55	73.78
Shot no	2 to 11	30 to 32	50 to 52	58 to 60
Delivered	213.066	232.501	215.271	221.652
Fine Particle Dose μg	44.675	52.097	48.675	52.872
Fine Particle Fraction %	20.968	22.407	22.611	23.854
MMAD	2.629	2.681	2.546	2.743
GSD	2.346	2.283	2.313	2.316

SykonaHaler - Ergonomic and Manual Assembly Modules & Test Module



Semi-Automatic Assembly Line Concept

Our **Assembly Modules** consist of four (**4**) **workstations** (named Module 1- 4), with intermittent manual transfer of parts and /or products between the parts sources, the workstations and any ancillary stations or units (e.g. coiling and blister insertion unit).

The material flow:

- is to be organized following the "**Milk-run**" **concept**, i.e., one worker checks the content of the individual workstations on a regular basis (e.g. every 20-30 minutes) and provides for refilling the parts supplies from bulk containers into workstation grasp boxes and for loading/unloading trays with pre-assemblies or finished assemblies or products, respectively.

Assembly:

- The workstations are designed according to ergonomic principles and are equipped with partly mechanized fixtures. The fixture equipment is designed to provide for safe operation and error avoiding assembly according to the **POKA YOKE principle**.
- Therefore e.g. the shape of the fixture and/or locating pins within the fixture allow for insertion and deposition of the correct parts to be mounted only in the correct position and orientation.

Why we offer this?

- We would like to offer our customers, for phase 1-3, **everything out of one hand!** And at a relatively low cost compared to the fully automatic version!

Semi Automatic Assembly Modules



Assembly Module 1: Workstation – Detail View



Schmidt Press →



Contracting Wheel
Ratchet



Contracting Wheel
Ratchet Gear

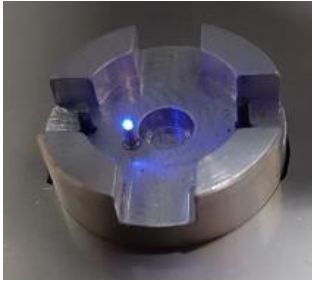


Contracting Wheel Arm



Finished Subassembly

Assembly Module 1- Assembly Detail View



Fixture Module 1



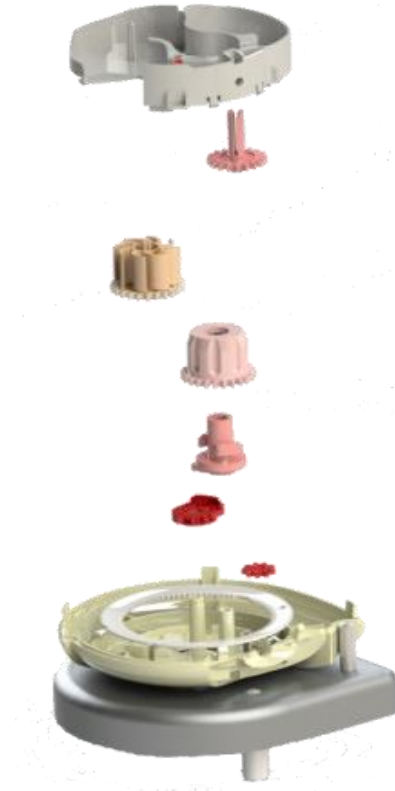
Schmidt Press for Contracting Wheel Assembly



Assembly Module 2: Workstation – Detail View



Assembly Module 2: Workstation – Detail View



9. Manifold

8. Base Wheel

7. Contracting Wheel Group

6. Index Wheel

5. Index Wheel Ratchet

4. Drive Wheel Gear

3. Idler Gear

2. Counting Wheel

1. Body Base

Assembly Module 2: Fixture 2.1



Fixture for the BodyBase
(Module 2.1)



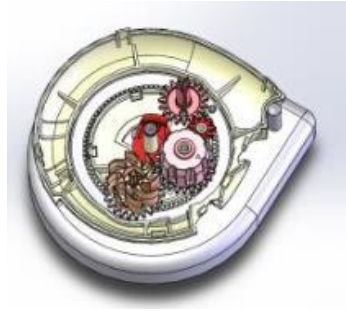
Assembly of gear box



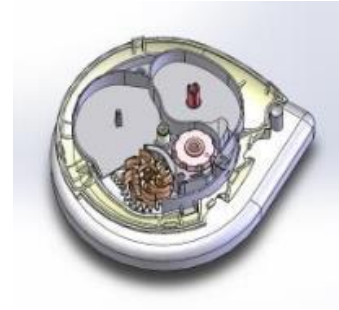
Assembly of counter wheel
and idler gear



Assembly of drive-, base
and index wheel



Assembly of contracting wheel

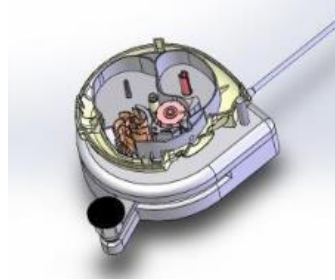


Finished Gear Box
Assembly

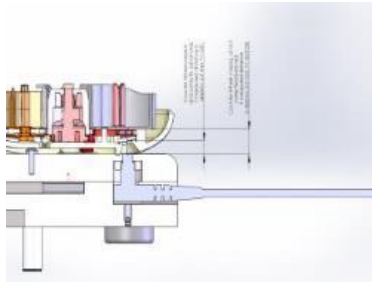
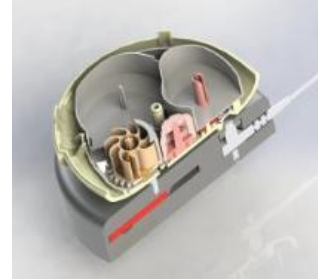
Assembly Module 2: Fixture 2.2



Fixture Module 2.2



Activation of the device to check the gear box function



Sensor to check the presence and correct placement of the counter wheel



The Green LED should light up.



In case the green LED does not light up, it means the Gear Box does not function properly.

Assembly Module 3: Workstation – Detail View



Assembly Module 3: Workstation – Detail View



Body Half Top



Pre-assembled
DPI Gearbox



Mouth Piece

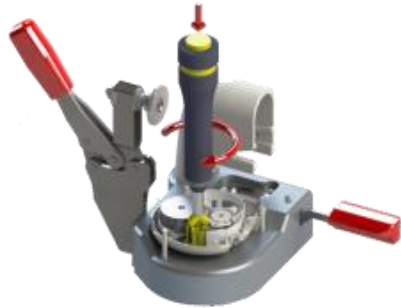


Outer Case

Module 3: Mouth Piece and Body Half Top Assembly



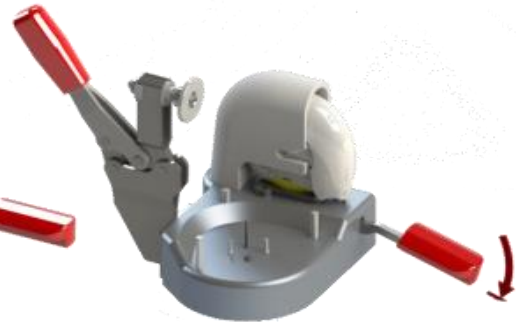
Module 3 Fixture



Tensioning the Blister Stripe using the torque wrench

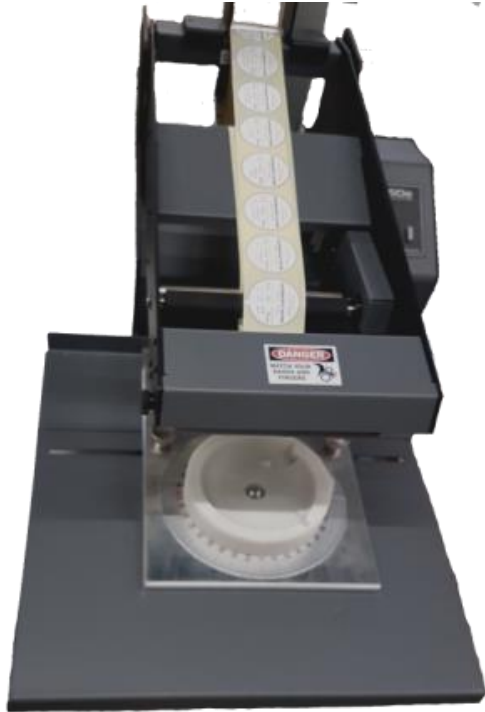


Body Half Top Assembly

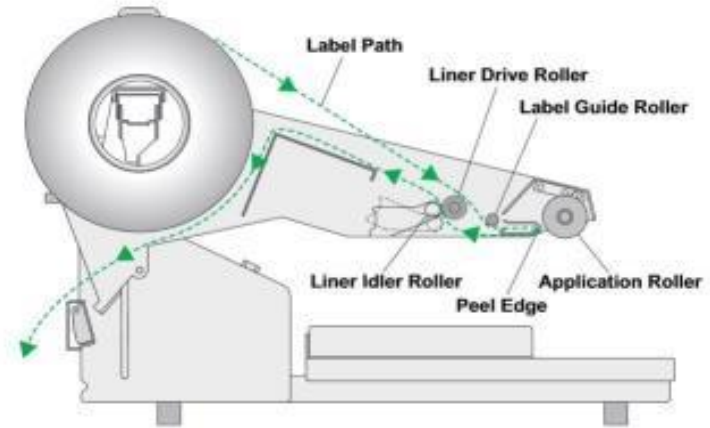


Mouthpiece Assembly

Module 3: Labelling



Label Path Diagram



Test Module 4: IPC Test Module – Final DPI Device Test



High Capacity Pump

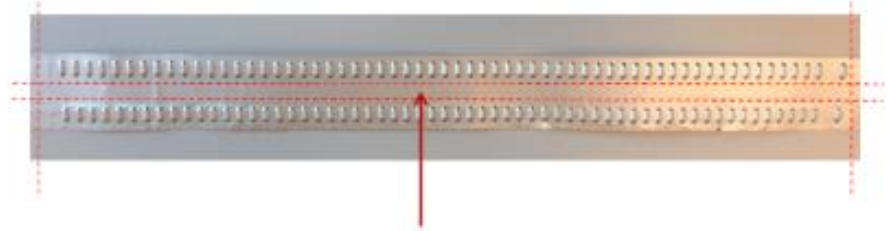
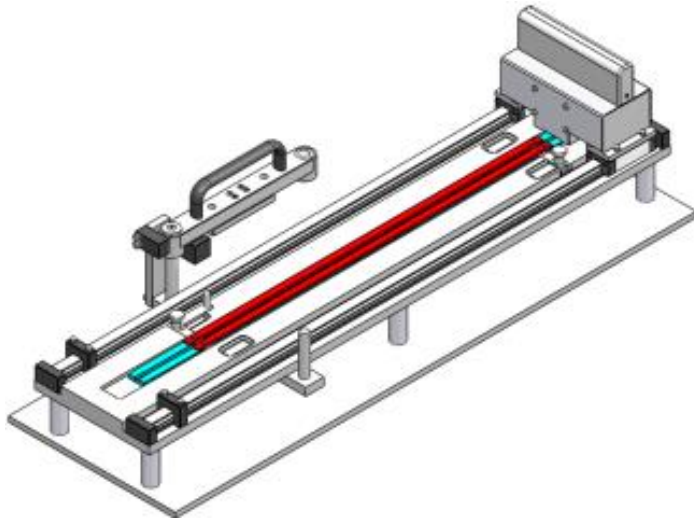


Flow Controller

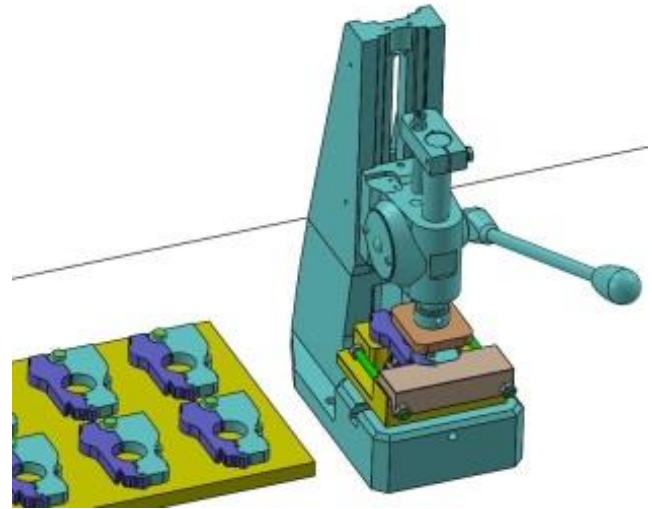
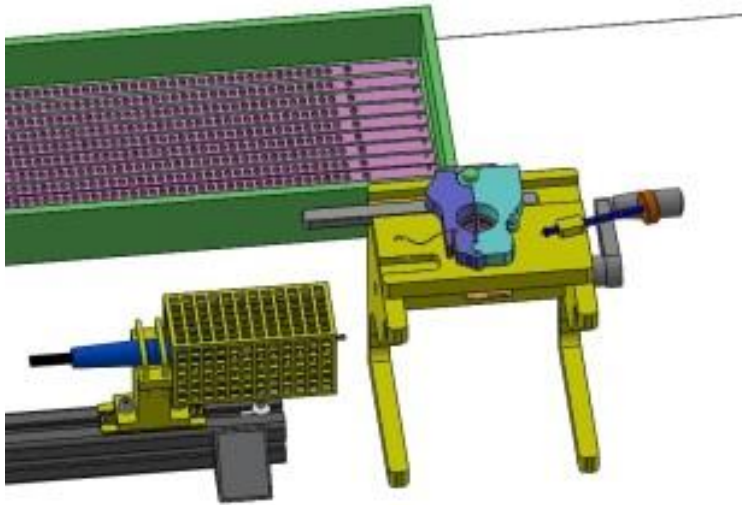


IPC Test Fixture

Assembly Manual Cutting of the Bister Strip



Coiling of the Bister Strip



Plastic Trays for Assembly Modules

Trays for storage of the Device parts



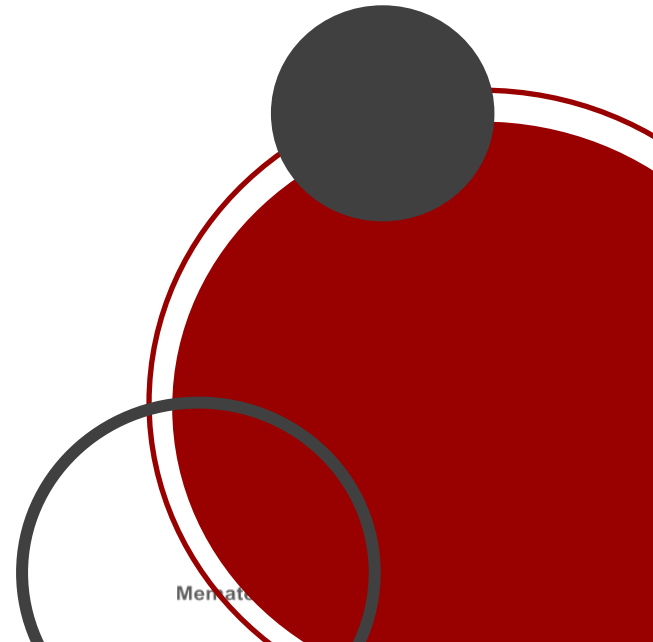
Universal Tray for Body Base, Pre assembled Gear Box, Final Assembled SykonaHaler prepared for final test (open mouth piece)



Tray for Manifold

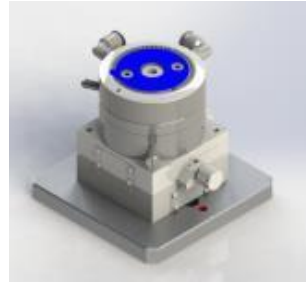
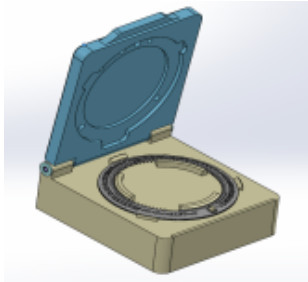
Annexes

- Other Services Offered
- References

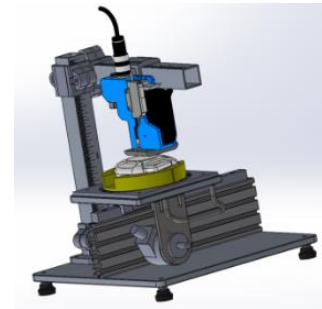


Other Services Offered

Counter Wheel Printing and Checking



Cover Printing and Checking (Logo and Var. Data)



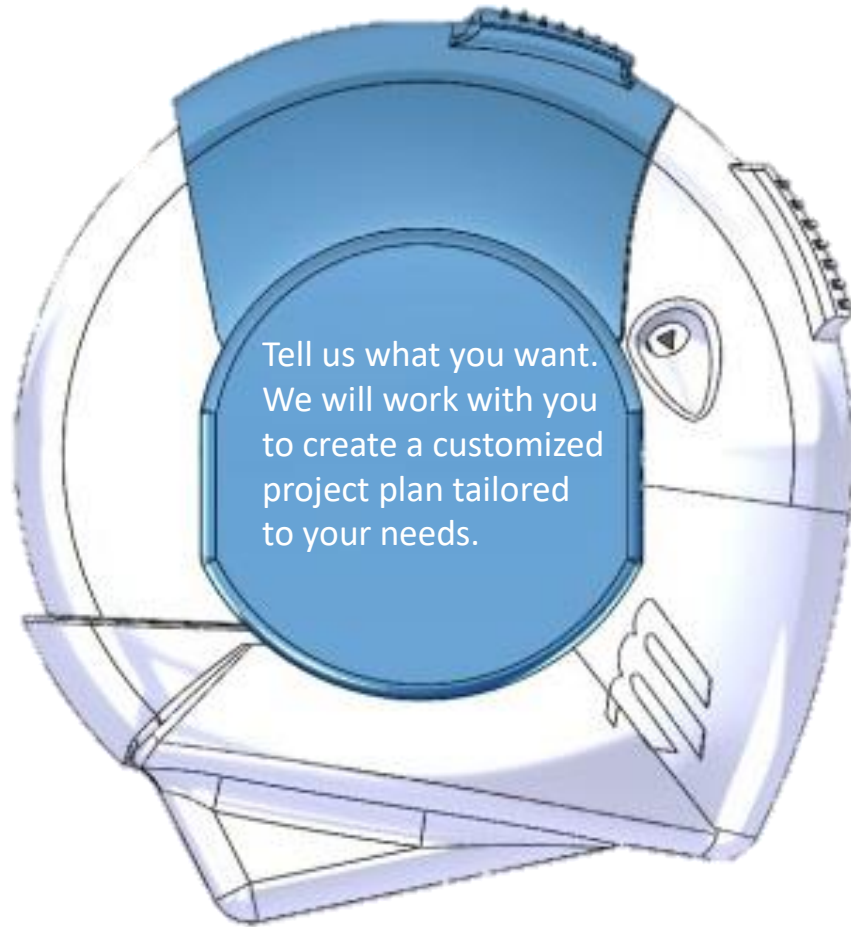
Other Services Offered

Trollys



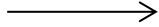
Other Services Offered

- Documentation
 - Molding Tools Specification documents
 - Validation and Qualification documents
 - URS, SRM, DDS, FMEA, FAT, IQ, OQ, etc.
 - Handling Study
 - Device Operation Instructions
- Powder formulation assistance in order to optimize the physical properties of the blend
- Assistance in filling machine set-up (optimization of content conformity)
- In-vitro testing of device (Emitted Dose, Fine Particle Dose, Air Flow, etc.)
- Supplier evaluations for:
 - Molding tool supplier
 - Plastic part supplier
 - Assembly machine supplier
- Product design, construction, function and specification as well as testing for MDPI and DPI inhalers
- Support in Regulatory Procedures – in both EU and USA

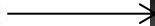


References

NATIVA

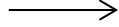


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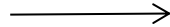


BEXIMCO PHARMA

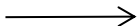
here's to Life



Zydus Cadila



dbi PHARMA



UniMed UniHealth Pharmaceuticals



BOSCH

ROHWEDDER
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CHEMO
Oral Care in Healthcare

HH Harro Höfliger

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