CERTIFICATE OF COMPLIANCE

CERTIFICATE OF ANALYSIS

FOR

INHALATION DEVICE

OSTREA INHALER

Inhaltsverzeichnis

1 FREIGABE FUNKTIONSSPEZIFIKATION / ÄNDERUNGSINDEX

Version	Datum	Freigabe		ÄNDERUNGEN /CHANGES
0.1	06.02.2019	Markus Mezger		Erstausgabe/ First Issue

Version	Datum	ÄNDERUNGEN /CHANGES
0.1	06.02.2019	Erstellung COA, COC für Ostrea Inhaler, Draft Version

2 REFERENZDOKUMENTE

Dokument /-herkunft	Version	Datum
Erstvorlage von Markus Mezger	0.1	21.04.2015
URS draft version	0.3	22.11.2018
FMEA draft version	0.1	16.12.2018

3 ABKÜRZUNGEN / ABBREVIATION

Allgemeine Abkürzungen / General Abbrevation

AN	Auftragnehmer
ASi	Actuator-Sensor-Interface (Feldbussystem)
BGV	Berufsgenossenschaft Vorschrift
CFR	Code of Federal Regulations
DIN	Deutsches Institut für Normung e. V.
EMV	Elektromagnetische Verträglichkeit
EN	Europäische Norm
FIFO	First In First Out (Speicherorganisationsprinzip)
FMEA	Failure Mode and Effect Analysis
GSG	Gerätesicherheitsgesetz
GMP	Good Manufacturing Practice
HF	Hochfrequenz
HMI	Human Machine Interface
IEC	International Electrotechnical Commission (Internationale Normungs Organisation
IPC	In Process Control, Industrie-PC
NFPA	National Fire Protection Agency
OPC	Open Process Communication Standard
SCADA	Supervisory Control And Data Acquisition (Linienleitsystem)
SOP	Standard Operation Procedure (Arbeitsanweisung)
UL	Underwriters Laboratory (Amerikanische Sicherheits- und Normen Organisation)
USV	Unterbrechungsfreie Stromversorgung
VDE	Verband der Elektrotechnik Elektronik Informationstechnik e.V.
XML	Extended Markup Language (Communication format standard)
21 CFR 11	Title 21 Code of Federal Regulations Part 11 (US-amerikanisches Bundesgesetz zum Thema „Electronic Records, Elektronic Signatures“)
DQ	Design Qualification (Designqualifizierung)
“as built”	“wie gebaut” d.h. der tatsächlichen Installation entsprechend
Electronic Record	Jede mögliche Kombination von Text, Graphiken, Daten, Bild- oder sonstigen Informationsdarstellungen in digitaler Form, die mit Hilfe eines Rechnersystems erstellt, modifiziert, gepflegt, archiviert, wiedergefunden oder verteilt werden.
GAMP	Good Automated Manufacturing Practice (Leitfaden der ISPE zur guten Herstellungspraxis mit automatisierten Systemen)
FAT	Factory Acceptance Test (Prüfung beim Hersteller
IQ	Installation Qualification (Funktionsqualifizierung)
OQ	Operational Qualification
PQ	Performance Qualification (Leistungsqualifizierung)
QMP	Qualification Master Plan
SAT	Site Accetptance Test (Prüfung am Installationsort)
SLC	System Life Cycle (Lebenszyklus eines systems)
OPL	Open-Point-List
URS	User Requirement Specification (Benutzeranforderung)
POP	Proof of Principle

3.1 Projekt Spezifische Abkürzungen / Project Specific Abbreviations

The 'definitions' section is used to define all terms and phrases which are used in the body of the specification but which may be ambiguous in their meaning. The definitions captured in this generic specification are likely to be required but care should be taken to capture any other words or phrases which require defining.

Active Ingredient	Active Ingredient The part of the formulation with therapeutic effect.
Delivered Dose	The mass of active ingredient received by the patient during a single inhalation. This can also be known as the Emitted Dose.
Device	The fully assembled inhaler (excluding all packaging).
Device Pressure Drop	A pressure drop created through the device by an inspiratory flow rate.
Dose Content Uniformity	The repeatability of the delivered dose during the lifetime of a device and between devices. Abbreviated to DCU.
Fine Particle Dose	The mass of active ingredient with an aerodynamic diameter of 5 microns or less received by the patient during a single inhalation. Abbreviated to FPD.
Fine Particle Fraction	The percentage of delivered dose with an aerodynamic particle size of 5 microns or less. Abbreviated to FPF.
FMECA	Failure Mode, Effects and Criticality Analysis – a bottom up risk management technique / design tool that systematically identifies failures that lead to hazardous conditions.
Formulation	The active ingredient stored in the inhaler and its associated lactose carrier.
FTA	Fault Tree Analysis – a top down risk management technique / design tool that uses hazardous conditions to systematically identify device or system failures.
Inhalation Path	The path of air into and out of the device and into the patient's mouth.
Metered Dose	The mass of active ingredient removed from the bulk reservoir during normal operation or for discrete dose devices - the mass of active ingredient contained in a

	discrete dose chamber. The metered dose for the capsule device is the capsule itself.
Nominal Dose	The label claimed delivered dose per normal operation, which is equal to the nominal, delivered dose.
Normal Operation	The operation of the device performing all the operating steps in the correct operating sequence and generating a device pressure drop of 4kPa. A 4kPa pressure drop represents a medium resistance inhaler as defined by the EP and USP. Where a low or high resistance inhaler is being specified the pressure drop values will need to be altered accordingly.
Nominal Actuation Orientation	[TBD]. This will be the orientation of the device during normal actuation.
Nominal Inhalation Orientation	[TBD]. This will be the orientation of the device during normal inhalation.
Patient	The person who uses the device to receive the formulation.
PIF	Median Peak Inspiratory Flow (PIF)
Particle Size Distribution	The distribution of particle sizes in the delivered dose.
RSD	Relative Standard Deviation = 100 x (Standard deviation / Mean).
Secondary Packaging	All external packaging surrounding the device during pre-sale storage.
Shot weight	The mass of formulation delivered from the device on a single actuation during normal operation.
S.G.	Specific Gravity = density of a substance / density of water at 4°C (1000kg/m^3).
Specification	A dose is defined as being delivered to specification if its fine particle dose is within ±20% of the fine particle dose during normal operation.

4 EINFÜHRUNG / INTRODUCTION

This document has been written as a detailed description for a dry powder inhaler (DPI) Ostrea inhaler device.

This document contains regulatory requirements and industry standards present at the time of writing. A careful check of all current requirements should be made prior to issuing the specification for a product. Where no regulatory or industry standards exist, Mematec Solutions has used other source materials and its experience of DPI design to set requirements.

Blue text is text that has been added for instructions on how to use the generic specification template. This does not form part of the generic requirements specification and should be removed from the tailored specification

4.1 Zielvorgabe des Dokuments / Objective of the document

The objective of this document is to define the requirements for the OstreaHaler and the Torus- dry powder inhaler. It provides the full set of requirements against which the system will be validated and, as such, forms the primary reference document for use during design and development.

5 RICHTLINIEN / REFERENCED DOCUMENTS

Where appropriate, sources or fuller explanations of requirements should be given. This section defines the abbreviations used for these references to reduce the amount of text required in the body of the specification.

These documents only form requirements to the extent explicitly stated wherever they are referenced in this document.

[ACPS]	Parametric tolerance Interval test for Delivered Dose Uniformity" Advisory Committee for Pharmaceutical Science October 2005
[ADULTDATA]	Adultdata: The handbook of adult anthropometric and strength measurements (Published by Product Safety and Testing Group (PSTG), 1998).
[BATT]	Directive 2006/66/EC of the European Parliament and of the Council on batteries and accumulators and waste batteries and accumulators
[BIO]	Draft Guidance for Industry - Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action: FDA, 2003
[CHILDDATA]	Childdata: The handbook of child measurements and capabilities (Published by PSTG, 1995).
[CHOKING]	BS EN 71-7:2002 - Safety of toys. Finger paints. Requirements and test methods.

	ASTM F963-07e1- Standard Consumer Safety Specification on Toy Safety.
[CYTO]	ISO10993-parts 1 to 18: 1997-2008 - Cytotoxicity.
[DOSE COUNTER]	Guidance for Industry - Integration of Dose-Counting Mechanisms into MDI Drug Products: FDA, 2003.
[DROP]	IEC 60068-2-32:1975 Environmental Testing- Tests.Test Ed: Free fall
[ELEC SAFETY]	IEC 60601-1 Medical electrical equipment.General requirements for safety. IEC 60601-1-1 Medical electrical equipment, collateral standard. Safety requirements for medical electrical systems. IEC 60601-1-4 Medical electrical equipment, collateral standard. General requirements for programmable electrical medical systems
[EMC]	IEC 60601-1-2 Medical electrical equipment, collateral standard. Electromagnetic compatibility:requirements and tests IEC 61000-4-2 2001 Electromagnetic compatibility: Testing and measurement techniques – electrostatic discharge immunity tests IEC 61000-4-2 2001 Electromagnetic compatibility: Testing and measurement techniques – Radiated , radio frequency, electromagnetic field immunity test.
[EMEA1]	Note for Guidance on Dry Powder Inhalers: CPMP, 1998.
[EMEA2]	Guideline on the pharmaceutical quality of inhalation and nasal products: CHMP, 2006
[EP]	European Pharmacopoeia, Sixth Edition, 2008
[EPAG]	Summary of test methods for use and misuse of inhalers: EPAG. Available from www.epag.co.uk/Inuse.htm
[GUIDANCE]	Draft Guidance for Industry - Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products: FDA,1998.
[IPAC-RS]	A Parametric Tolerance Interval Test for Improved Control of Delivered Dose Uniformity of Orally Inhaled and nasal Drug Products: IPAC-RS, Nov. 2001.
[ISO13485]	BS EN ISO 13485: 2003 - Quality Systems - Medical Devices - particular requirements for the application of EN ISO 9001.

[ISO20072] Draft BS ISO 20072 2007 Aerosol drug delivery devices design verification – Requirements and test methods

[ISO9001] Quality Systems, BS EN ISO 9001: 2000 (will be updated 2008

[ITI] ISO10993-1-17: 1992-2007 – Intracutaneous Toxicity or Irritation.

[LABEL] Guidance on Medical Device Patient Labelling; Final Guidance for Industry and FDA reviewers: FDA, 2001.

[LIGHT] BS 2782-5, Method 540G:1995: Methods of testing plastics. Optical and colour properties, weathering. Methods of exposure to laboratory light sources. Open flame carbon-arc lamps.

[MDD] Medical Device Directive, 93/42/EEC, 1993.

Essential requirements Annex 1/93/42/EEC

[PARTICULATES] “Best Practises for Managing Quality and Safety of Foreign Particles” J Blanchard et al Pharmaceutical Research 24.3 2007 471-479

”Measurement and Identification of Foreign Particles in a QbD Environment Streamlining with Efiicient Analytical Methods” O.Valet and M. Lankers Respiratory Drug Delivery 2008

“Proposal for Foreign Particles Testing in Orally Inhaled and Nasal Drug Products” J. Hart Respitory Drug Delivery 2004

[OLDERADULT] Older Adultdata: The handbook of Measurements and Capabilities of the Older Adult (Published by PSTG,2000).

[QSR] Current Good Manufacturing Practice (cGMP) for Medical Devices & In Vitro Diagnostic Products - Quality Systems Regulation, 21 CFR Part 820, FDA, April 2008.

[RECYCL] ISO 14021:1999 Environmental Labels and Declarations

[ROHS] Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the “Restriction of the Use of certain Hazardous Substances in electrical and electronic equipment”

[Control] Directive 21CFR 820.30 for US required Design controls

[SENS] ISO10993-1-17: 1992-2007 – Sensitization.

[USP] United States Pharmacopoeia 31, 2008.

[VENTILATION] BS 7272-1:2000 - Writing and marking instruments. Specification for safety caps.

[VIBRATION1] IEC 60068-2-64: 1993- Environmental testing. Test methods. Test Fh. Vibration, broad band random (digital control) and guidance

IEC 60068-2-27: 2008 Environmental testing.Test Ea and guidance: Shock

[VIBRATION2] IEC 60068-2-6: 2008- Environmental testing. Test methods. Test Fc. Vibration (sinusoidal).

IEC 60068-2-7: 1993 - 60068-2-7: 1983 - Environmental testing. Test methods. Test Ga and guidance. Acceleration, steady state.

IEC 60068-2-29: 1993 - Environmental testing. Test methods. Environmental testing procedures. Tests. Test Eb and guidance. Bump.

US Standards:

ASTM D3332-99 (2004)– Standard Test Methods for Mechanical-Shock Fragility of Products, Using Shock Machines.

ASTM D3580-95 (2004)– Standard Test Methods for Vibration (Vertical Linear Motion).

ASTM D5112-98 (2003)– Standard Test method for Vibration (Horizontal Linear Sinusoidal Motion) Test of Products.

Electrical Standards:

IEC 60601-1: 2005 Medical Electrical Equipment- Part 1: General Requirements for Safety.

[WEEE] Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on “Waste Electrical and Electronic Equipment”

[FDA] Draft Guidance from 22. June 2011. Applying Human Factors and usability engineering to optimize medical device design

6 EINLEITUNG/ GENERAL DESCIPTION

6.1 Anwendungsbereich / Area of Use:

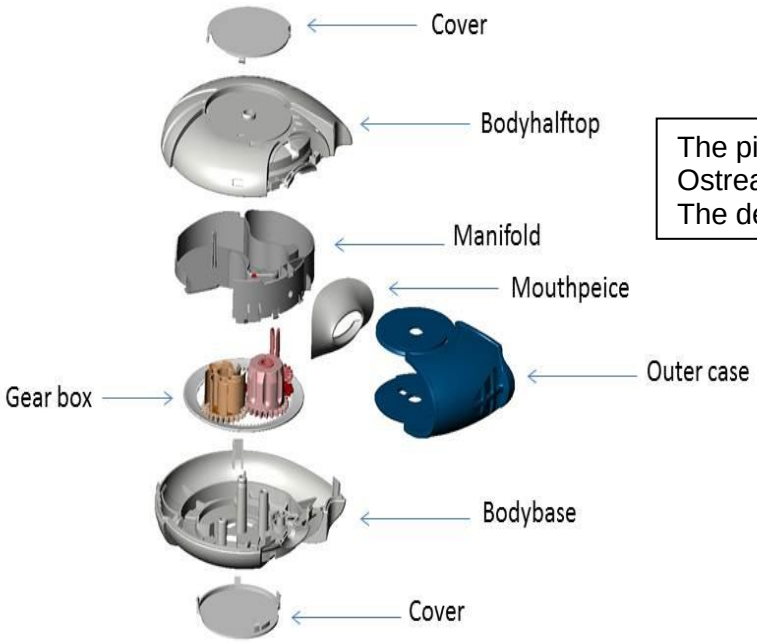
Blister based device for Seritide.
Seretide contains two active ingredients, salmeterol and fluticasone propionate:-salmeterol is a long-acting bronchodilator. Bronchodilators ensure that the airways in the lungs remain clear. This makes it easier to inhale and exhale air. The effect lasts at least 12 hours. Fluticasone propionate is a corticosteroid that reduces swelling and irritation in the lungs.

7 PATENTE:

Ostrea Patente which are applied.

„EU- Geschmacksmuster" 002988923-0001
„Designschutz in D" 402015201985.8

8 MODULARER AUFBAU, MODULAR STRUCTURE



The picture shows the internal parts of Ostrea Inhaler device with all components. The device is modular built.

Standard:

Varianten/ Variants:

Blister strip 61 cavity and later 31 cavities. 31 Cavity is not part of initial design order
Only the Counter wheel needs to be changed. Instead of 60 filled cavities we will show 30 filled cavities.

Optionen/ Options:

Different strength of Seritide

9 PACKAGING

The Device Ostrea will be available full assembled and delivered in bulk. The device is packed in a PE Bag. The number of device per bag is 500x.

10 SHIPMENT OF THE DEVICE

- Shipment procedure

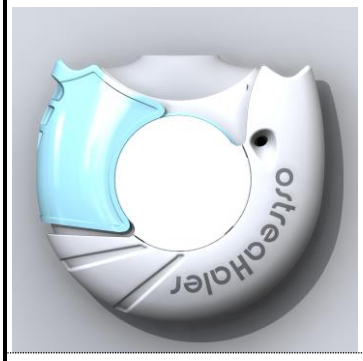
The Device will be shipped in 1x cartons with the amount of 250 Devices. The Dimension of the carton is: 0,6m³ (dimension can be varied from Customer to customer)

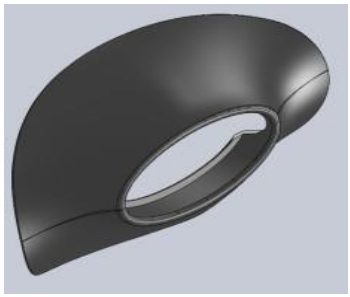
11 STABILITY OF THE DEVICE

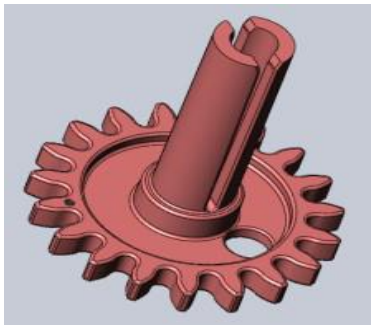
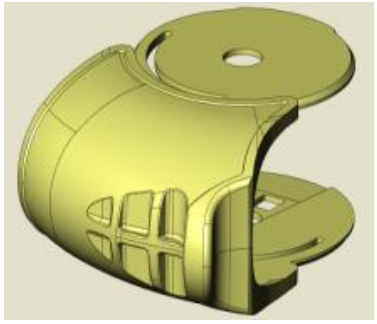
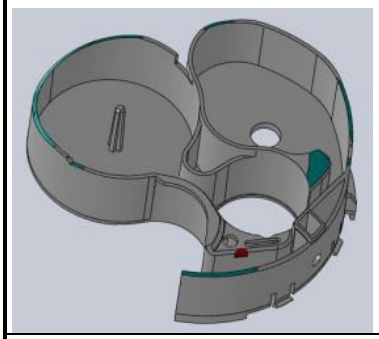
The Device and is selected materials are designed for a minimum time of storage in ambient temperature of minimum 2 years. The stability test must be performed at the customer side due to the local manufacturing of the blister strip. Main parameters influencing the stability of the blister strip are the parameter: Heating Temperature, Time and Pressure.

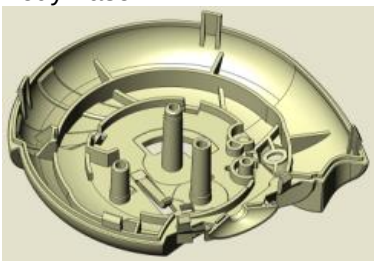
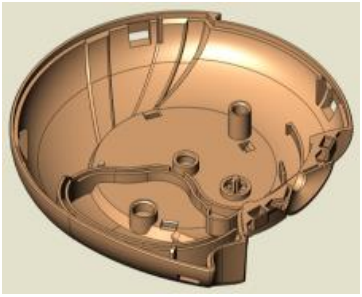
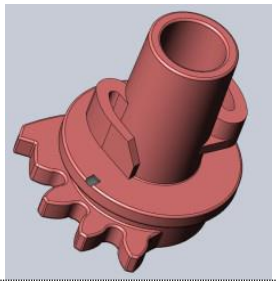
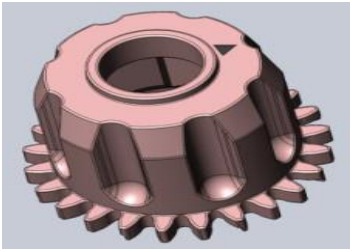
12 MATERIAL SELECTION AND CERTIFICATES

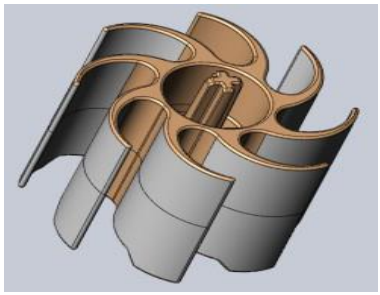
Description of the materials which are used.

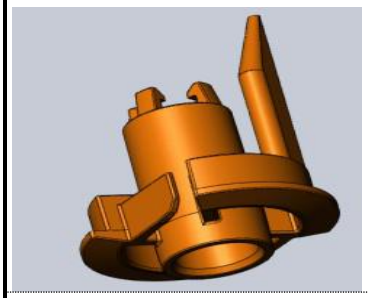
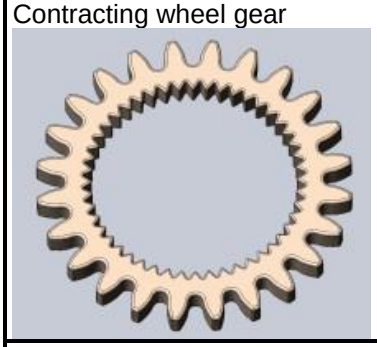
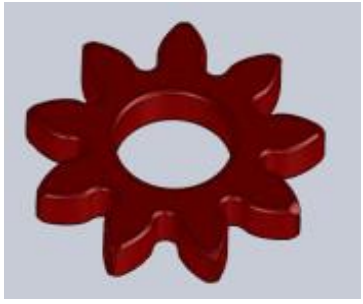
Description of the materials and components:
 	
Ostrea Inhaler
	Device, blister based, called OstreaHaler
	
	 
		Desciption:
		
		- Dimensions, Sizes,
		- ø:approx. 86mm, W:approx.30mm Weight: 65g
		- Material: plastic housing with Alu -Alu Blister
		- Ambient conditions:
		  - RH 35-65%
		  - T:23°C ±5°C
		- Tolerances are defined in mematec parts drawings
		- Colour Body Base: White

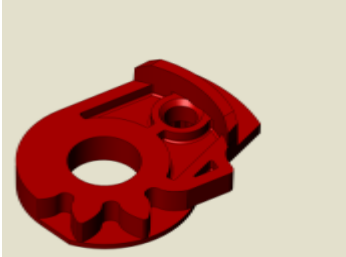
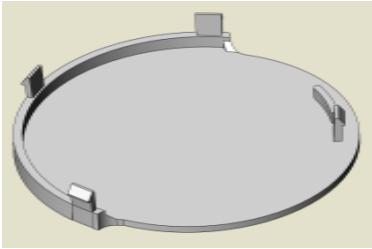
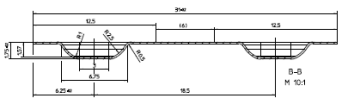
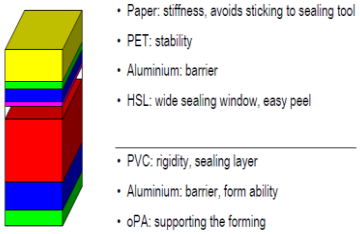
Description of the materials and components	Pulver, Powder: Seritide in different strength. Responsible for the Data are the distributing Company.	Description: Description - Mass: 12,5mg - Density: depending on the API and Lactose - Moisture sensitivity: needs to be protected against moisture - Melting point: depending on the Powder Blend - Segregation: yes due to blend - Particle size: 2-100µ - Particle size distribution: depending on the Powder Blend
Description of the materials and components Mouthpiece	Part 1 Mouth Piece  Part in contact with patient requires FDA confirmation	Description: - Dimensions: 24.70mm x 45.6mm x 13.42mm - Material: FDA Confirm PP - Colour: white - Environmental conditions: 15-85% RH and T: -10°C - 45°C - Surface: electro- polished - Density = 0.001 g/mm3 - Mass = 1.2g - Volume= 1354.72 mm3

Description of the materials and components Base Wheel	Part 2 Base Wheel 	Description: - Dimensions: L= 21.2mm , ø= 18.35mm - Material: No FDA confirmed POM - Color/ Color: white - mass = 0.7 g - Environmental conditions: 15-85% RH and - Temperature: -10°C - 45°C - Surface: Line polish RZ 1 - Hole for mounting position
Description of the materials and components Outer case	Part 3 Outer case 	Description of the - Dimensions: 66.78mm x 49.62mm x27.80mm - Material: FDA Confirm ABS - Colour: white - Environmental conditions: 15-85%RH - Temperature: -10°C - 45°C - Surface: polished - Density = 0.001 g/mm3 - mass = 10.1 g - Volume = mm3
Description of the materials and components: Manifold	Part 4 Manifold 	Description - colour: white - Enviroment condition: 15-85%RH - Temperature: -10°C – 45°C - Surface: polished Puffer for empty blister strip and puffer for blister strip with 61 filled powder cavities. - Density = 0.001 g/mm3 - Mass = 9.1 - Volume = 9100 mm3 -Material: FDA confirm POM
Description of the materials and components Counting Wheel	Part 5 Counting Wheel 	Description -60 figures in total, 55figures in black printing. - Figures 5-1 in red printing. - Printing in tamp print technology - No- Stop function end of strip. -Key hole for assembly position - Counting wheel counts remaining shots left - Material in ABS - Letter Size 2,5mm -mass = 1.2 g

Description of the materials and components Body Base	Part 6 Body Base 	Description of the - Material: FDA Confirm ABS - colour: white - Enviroment: 15-85%RH - Temperature: -10°C – 45°C -Surface: polished - Density = 0.001 g/mm3 - Mass = 17.5 g -Volume = 17500 mm3
Description of the materials and components Body Base half top	Part 7 Body Base half top 	- Material: FDA Confirm ABS - Farbe/colour: white - Enviroment condition: 15-85%RH - Temperature: -10°C – 45°C - Surface: polished - Density = 0.001 g/mm3 - Mass = 15.5g - Volume = 15500 mm3
Description of the materials and components Index Wheel ratchet	Part 8 Index Wheel ratchet 	Description - Diemensions: L= 19.3 mm , ø= 18.195mm - Material: None FDA Confirm POM - Colour: white - mass = 1.3g - Enviroment condition: 15-85% RH - Temperature: -10°C – 45°C - Surface: polished Mark for assembly position
Description of the materials and components Index Wheel	Part 9 Index Wheel 	Description - Dimensions: L= 16.50mm , ø= 22.74mm - Material: None FDA Confirm POM - Colour: white - mass = 2.3 g - Enviroment condition: -15-85% RH - Temperature: -10°C – 45°C - Surface: polished Mark for assembly position

Description of the materials and components Contracting wheel arm	Part 10 Contracting wheel arm 	Description - Diemension: L= 15.3mm , ø= 20.35mm - Material: None FDA Confirm POM - Colour: white -mass = 1.5 g - Enviroment condition: 15-85% RH - Temperature: -10°C – 45°C - Surface: polished Mark for assembly position

Description of the materials and components Contractiong wheel ratchet	Part 11 Contractiong wheel ratchet 	Description - Dimensions: L= 19mm , ø= 17mm - Material: None FDA Confirm POM - Colour: white - mass = 0.7 g - Enviroment condition: 15-85% RH - Temperature: -10°C – 45°C - Surface: polished - Mark for assembly position
Description of the materials and components Contracting wheel gear	Part 12 Contracting wheel gear 	Description - Diemension: L= 2mm, ø= 22.4mm - Material: None FDA Confirm POM - Colour: white - mass = 0.4 g - Enviroment condition: 15-85% RH - Temperature: -10°C – 45°C - Surface: polished - Mark for assembly position
Description of the materials and components Idler Gear	Part 13 Idler Gear 	Description - Diemension: L= 2mm, ø= 10.52mm - Material: FDA Confirm ABS - Farbe/colour: white - mass = 0.6 g - Enviroment condition: 15-85%RH - Temperature: -10°C – 45°C - Surface: polished Assembly position will be fixed by pin. The fixation will keep all gear box parts in the starting position. Will hold the counting wheel in position in pre assembly, avoids falling out of housing

Description of the materials and components Drive Wheel gear	Part 14 Drive Wheel gear 	Description - Material: None FDA Confirm POM - Colour: white - mass = 0.6 g - Enviroment condition: 15-85% RH - Temperature: -10°C – 45°C - Surface: polished Mark for assembly position
Description of the materials and components Cover	Part 15 Cover 	Description - Diemension: L= 3.1mm , ø= 21.3mm - Material: None FDA Confirm POM - Colour: white - mass = 1.5 g - Enviroment condition: -15-85% RH - Temperature: -10°C – 45°C Surface: Polished for laser printing of variable and fixed data.Eroded surface for better grip while handling the device
Description of the materials and components Blister Strip	Part 16 Blister Strip  	**Material Lid foil:** **Lid foil** Paper 50 g/m² PET 12 µm Aluminum 20 µm HSL-peelable 7 g/m² Locating mandrel in HH machine: 150mm Film width: 117 mm Blister strip length: 710 mm **Material Base Foil:** mandrel in HH machine: 150mm Film width: 115 mm Blister strip length: 710 mm **Base foil** PVC 100 µm Aluminium 45 µm oPA 25 µm

13 RESPIRATOY DEVICE RESISTANT DATA

Device Resistent Data

Flow Rate in l/min	Pressure Drop P1 in kPa	Pressure Drop P2 in kPa	Pressure Drop P1 in kPa	Pressure Drop P2 in kPa
	Mematec MDPI		GSK Originator Device	
20	1,65	0,88	1,60	0,36
40	2,10	0,88	2,40	0,36
60	4,05	0,88	3,7	0,36
80	6,2	0,88	5,4	0,36
90	7,35	0,88	6,5	0,36

Salmeterol

Flow Rate in l/min at 4 kPa	Delivered dose in µg	Fine particle dose in µg	Fine particle fraction in %	MMAD	GSD
74,6	49,13	8,322	16,939	2,668	2,433
74,55	48,925	7,725	15,790	2,570	2,471
72,62	50,463	9,407	18,642	2,523	2,445
74,76	46,405	8,890	19,157	2,371	2,511

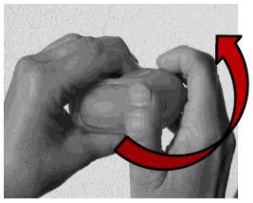
Fluticasone

Flow Rate in l/min at 4 kPa	Delivered dose in µg	Fine particle dose in µg	Fine particle fraction in %	MMAD	GSD
74,6	213,066	44,675	20,968	2,629	2,346
74,55	215,271	48,675	22,611	2,546	2,313
72,62	241,113	59,638	24,734	2,569	2,267
74,76	211,853	55,958	25,223	2,393	2,398

14 USER DESCRIPTION:

1

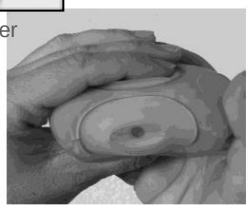
1. Open the cover



To open your OstreaHaler, hold the body base in one hand and put the thumb of your other hand on the thumb ring. 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.

2

2. Slide the lever



Hold your OstreaHaler with the mouthpiece towards you. You can hold it in either your right or left hand. This placed a dose of your medicine in the mouthpiece. Every time mouth piece cover is pulled back a cavity is opened inside and the powder made ready for you to inhale.

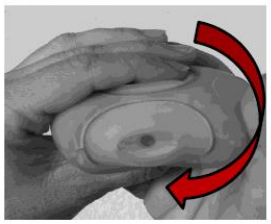
3

3. Inhale

Hold the OstreaHaler away from your mouth, breathe out as far as is comfortable. Do not breath into the OstreaHaler. Put the mouthpiece to your lips; breathe in steadily and deeply through the OstreaHaler, not through your nose. Remove the OstreaHaler from your mouth. Hold your breath for about 10 seconds or for as long as is comfortable.

4

4. Slide the thumb grip back



To close the OstreaHaler, slide the thumb grip of the mouth piece cover 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 is reset. Your OstreaHaler is now ready for you to use again.

15 ENVIROMENTAL REQUIREMENTS

Description
Device will deliver doses to specification and have no visible defects when operated in an environment of 18°C to 28°C at 25%R.H. to 75%R.H. [ISO20072] (This simulates 'in use' conditions only.)
Device will deliver doses to specification and have no visible defects when operated in an environment of 5+/- 3°C and 40+/- 2°C at 50%R.H. [ISO20072]
Device will operate to specification when stored below 0°C for at least 3 hours and then immediately used [EMEA2 4.2.1.15].
Device will deliver doses to specification when operated in an environment of between 10% and 90% R.H., at 25°C. (This requirement is recommended due to variation of surface charge and brittleness of capsules with ambient humidity.) [EMEA1, 2.4.5], [EMEA2 4.2.1.17].

15.1 GMP – Requirements / Hygiene

Funktions- Beschreibung
Device will not require cleaning during normal use. Cleaning of the device is possible using regular clean water
Device will have a Mouth Piece cover to protect the mouth Piece of dust and dirt
Device will deliver a dose to specification immediately after the patient cleans the device as per the cleaning instructions for the device [EPAG]. For example, cleaning the device with a cloth will not leave a static charge on it that would prevent the device from subsequently delivering a dose to specification.

15.2 Environment Protection of the Device

Description of fulfilled requirements:
Device will be RoHS confirm
Device will be Reach Declaration confirm
Device will be Packaging and Packaging Waste confirm
Device will be WEE- Declaration confirm

15.3 Moisture

Will deliver doses to specification if there is a delay of up to 60 seconds between actuation and inhalation.

15.4 Partikel / Particulates

There are currently no clear guidelines on the particulate requirements for inhalation products.

Funktions- Beschreibung
Should not contain any removable parts that may be classified as a choking hazard as defined by the Small Parts Cylinder criterion detailed in [CHOKING/ Verstopfen]. There are currently no guidelines specifically addressing choking hazards for medical devices. The choking hazard presented by a removable part can be mitigated by ventilation i.e. allowing airflow through the part to delay asphyxiation pending medical intervention [VENTILATION]. However, it is recommended that removable parts be designed to be large enough to not present a choking hazard as opposed to seeking to mitigate this risk through ventilation.
Shall allow no more than 50µg/day of foreign particles having aerodynamic diameter less than or equal to 10 µm to become detached from the device (equivalent to 5% of the National Ambient Air Quality Standard) [PARTICULATES].
Shall allow no more than [TBD] particles with longest axis greater than [TBD] µm in length to become detached from the device and reach the inhalation path during [TBD] normal operations. (The dimension and number used is not stipulated by regulatory bodies - it is a patient confidence issue).
Shall allow no more than [TBD] particles with longest axis greater than 100µm in length to become detached from the device and reach the inhalation path during [TBD] normal operations following an impact as defined in section 6.1. (The dimension and number used is not stipulated by regulatory bodies - it is a patient confidence issue).

15.5 Qualitätsmanagement / Quality Systems

Description
Device is, manufactured and distributed in accordance with the following reference documents: [QSR], [ISO9001], [ISO13585], [MDD].
Device is designed accordance with ISO 13485 (Design and manufacturing of medical devices)
Device is designed accordance with *MDD 93/42/EWG (Medizinprodukte Richtlinie/ Medical Device Directive)*

15.6 Recycling Information

Description
Device has appropriate recycling information marked on product as defined in URS
Device has appropriate colours according to the convention defined in URS

15.7 Herstellung / Manufacturing

Molding/ Components & Subassembly

Description
Plastic parts to be molded in a room with the classification ISO 8, 100.000
Device is assembled in a room with the classification ISO 8, 100.000
Plastic parts will be final checked in a room with the classification ISO 8, 100.000
Should, where necessary, have fully functional major subassemblies self- contained for transportation without the need for jigs and fixtures.
The Device Ostrea have all non-metallic parts & subassemblies made under grade C EU GGMP cleanroom conditions (compares to US Federal standard 209E class 10,000).
Molding tool material is done in stainless steel. The air path is done in stainless steel. Alternative standard steel in high quality.
No lubrication and mold release agent are used for the molding process

15.8 Documents to be Delivered

Allgemein / General

Description
The following documents are available with the device Ostrea Ellipse. Layout Drawing of the device with the dimension Plastic Parts of the device with Material Certificates Metal parts with Material specification CE Confirmation Declaration Device History File

15.8.1.1 Bedienungsanleitung / Operation Manual

Description
The handling of the device is shown in the handling instruction. A handling Video can be down loaded on the Mematec solution homepage