CERTIFICATE OF COMPLIANCE

CERTIFICATE OF ANALYSIS

FOR

INHALATION DEVICE

NESAT

Inhaltsverzeichnis

1 FREIGABE FUNKTIONSSPEZIFIKATION / ÄNDERUNGSINDEX

Version	Datum	Freigabe		ÄNDERUNGEN /CHANGES
0.1	07.02.2016	Markus Mezger		Erstausgabe/ First Issue

Version	Datum	ÄNDERUNGEN /CHANGES
0.1	07.02.2016	Erstellung COA, COC für Nesat

2 REFERENZDOKUMENTE

Dokument /-herkunft	Version	Datum
Erstvorlage von Markus Mezger	0.1	21.04.2015
URS draft version	0.3	22.11.2016
FMEA draft version	0.1	16.12.2016

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) Nesat 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

Development of a DPI (Dry Powder Inhaler). The device must be approved as a medical device. This means that a CDT is part of the development task. The project consists of a device with 2 active ingredients. The URS only describes the tasks of the DPI.

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:

The active ingredients are: Spiriva and Foradil for hard capsules size 3 with a filling weight of 5-10mg.

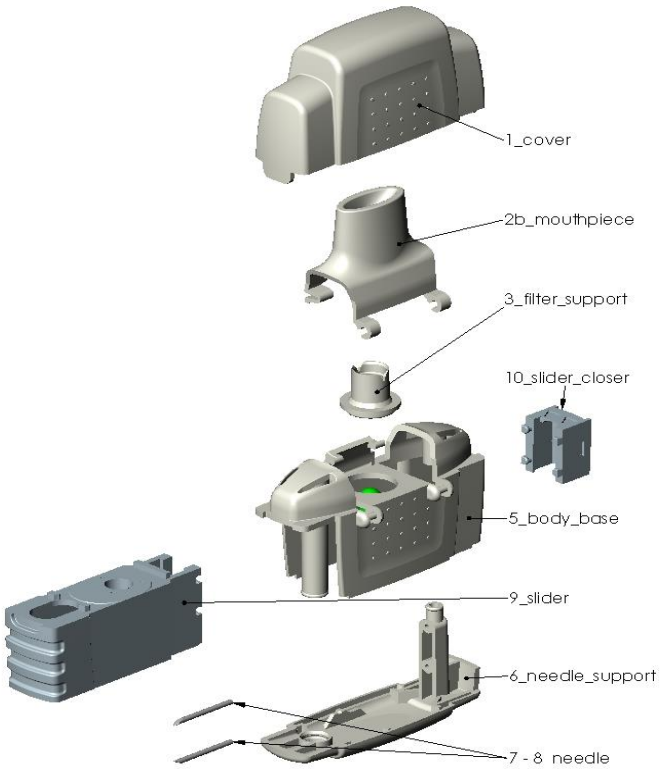
7 PATENTE:

Nesat Patente which are applied.

„EU- Geschmacksmuster" 002712638-0001
„Designschutz in D" 402015201419

Patents are registered.
Patent with the number: 004524205-0001 is protecting the design of the Nesat Internationally.
Patent with the number: 402015201419 is protecting the design of the Nesat in Germany.

8 MODULARER AUFBAU, MODULAR STRUCTURE



The picture shows the Nesat device with all components. The device is modular built.

Optionen/ Options:

Colour for Slider: RAL 5014 Pigeon blue.

9 PACKAGING

The Device Nesat 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

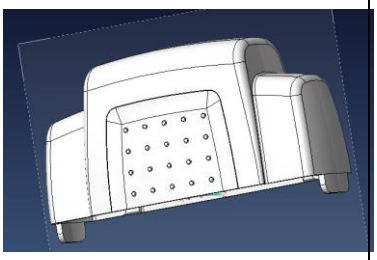
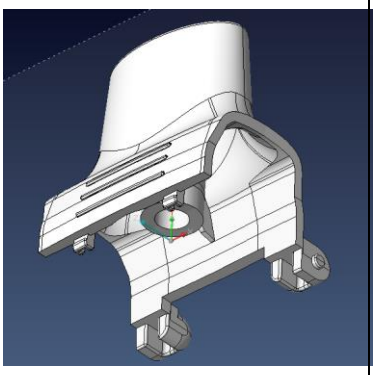
The Device will be shipped in 1x cartons with the amount of 1000 Devices. The Dimension of the carton is: LxBxH in cm (dimension can be varied from Customer to customer)

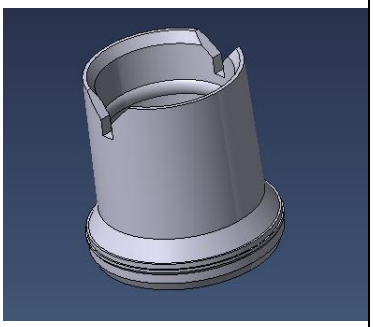
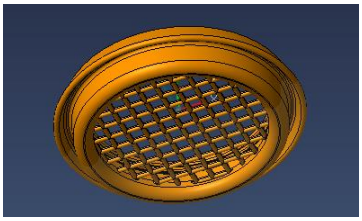
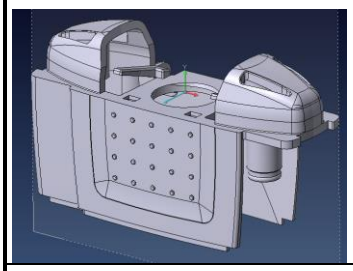
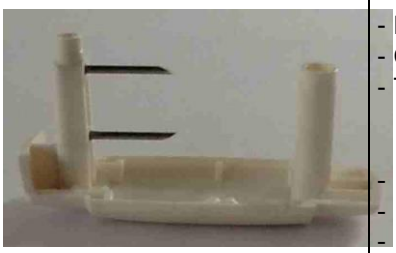
11 STABILITY OF THE DEVICE

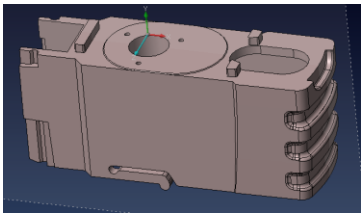
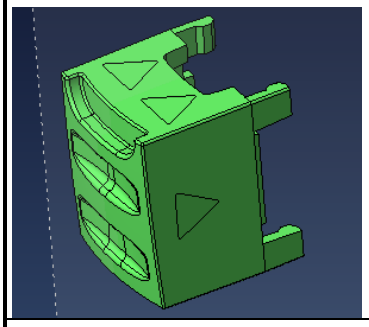
The Device and is selected materials are designed for a minimum time of storage in ambient temperature of minimum 2 years.

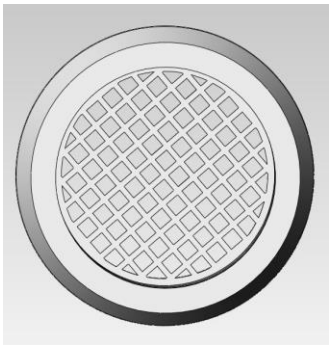
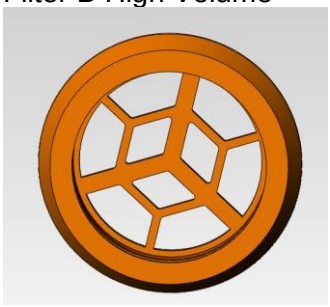
12 MATERIAL SELECTION AND CERTIFICATES

Description of the materials which are used.

Description of the materials and components: Nesat	Nesat Device consisting of : 1. Mouthpiece cover 2. Mouthpiece 3. Filter support 4. Filter 5. Body base 6. Needle support with needles 7. Slider 8. Slider closer 	Desciption: - Dimensions, Sizes, - 66,1mm x 69,9mm X 26,8mm - Weight: 37,9 g - Material: ABS/FDA and PEHD - Ambient conditions, RH 50% and T - Tolerances are defined in mematec parts drawings - Colour Body Base: RAL: 9003 Signal White - Colour Needle support: RAL 5014 Pigeon blue
Description of the materials and components Mouthpiece Cover	Part 1 Mouthpiece Cover 	Description: - Dimensions: 70mm x 38mm x 23,5mm - Weight: 8 g - Material: ABS - Colour: White / White RAL: 9003 - To cover the mouth mouth piece from dust and dirt
Description of the materials and components Mouthpiece	Part 2 Mouth Piece 	Description: - Dimensions: 33,10mm x 35,90mm - Weight: 4,8 g - Material: ABS , FDA - Colour: RAL 5014 Pigeon blue - Surface polished. - Integrated plastic filter. The mouthpiece must snap securely into the body base. The catch must be torsion-proof. - The mouthpiece must be elliptical to allow intuitive use

Description of the materials and components Filter support	Part 3 Filter support 	Description: - Dimensions: L=12,11mm, Ø = 11,92mm - Weight: 0,3 g - Material: ABS , FDA - Colour: White / White RAL: 9003 - Ambient conditions, RH and T - Filter support must be fixed into the mouth piece
Description of the materials and components Filter in Standard Execution	Part 4 Filter 	Description of the - Dimensions: L= 3,96mm, Ø= 16,7mm - Material: PEHD, FDA - Colour: White / White RAL: 9003 - Ambient conditions, RH and T - Filter is fixed into filter support. There are different sizes of filters
Description of the materials and components: Body base	Part 5 Body base 	Description Dimensions: 68,88mm x 39,76mm x 27,07mm - Weight: 9,8 g - Material: ABS, FDA - Colour: White / White RAL: 9003 - Ambient conditions, RH and T Check the parallelity of the needle. Piercing 120x HPMC capsules size 3. Needles must stay in exact position.
Description of the materials and components Needle support with needles	Part 6 Needle support with needles 	Description: Dimensions: 67,84mm x 33,40mm x 23,09mm - Material: PEHD, FDA - Colour: White / White RAL: 9003 - The needle tips must lie in the symmetry axis in vertical form so that the capsule is pressed into the chamber. - Position/distance: 12.20 ±0.05 - Mounting depth:5mm - Needle length pressed in: 16,5 ±0.3 - Weight: 4,6g - Needle must close tightly in guiding direction to avoid air leakage - Needles must be pressed in at a defined length. - Needles have to be pressed in parallel to each other without any need for intervention.

Description of the materials and components Slider	Part 7 Slider 	Description of the - Dimensions: 58,56mm x 26,05mm x 18,95mm - Weight: 8,9 g - Material: ABS, FDA - Colour: RAL 5014 Pigeon blue - Ambient conditions, RH and T - Check the parallelity of the needle. Piercing 120x HPMC capsules size 3. Needles must stay in exact position.
Description of the materials and components: Slider Closer	Part 8 Slider closer 	Description - Dimensions: 13,14mm x 17,25mm x 13,89mm - Weight: 1,2 g - Material: ABS - Colour: RAL 5014 Pigeon blue - Ambient conditions, RH and T - Check the parallelity of the needle. Piercing 120x HPMC capsules size 3. Needles must stay in exact position.
Description of the materials and components Capsule Size 3		Description Hard Gelatin or better HPMC capsules consisting of two parts. Upper part and lower part. The lower part is inserted into the upper part. Manufacturer: -Qualicaps, Capsulgel and ACG Description of the Tolerances Qualicaps: Tare weight: 50mg ±5mg Size tolerance: l:15,8mm ±0,3mm (closed) Outer ø: lower part: 5,56mm upper part: 5,82mm Tolerances Capsugel: Tare weight: 49mg ±4mg Size tolerance: l:15,5mm ±0,3mm (closed) Outer ø: lower part: 5,57mm upper part: 5,83mm

Description of the materials and components Needle	Kritische Herstellung der Nadel aus 1.4301 	Description of the Needle with the dimensions: Ø1,5mm Length:21,5 ±0,2mm Material 1,4301 Weight: 0,24g the following must be fulfilled during installation: -parallelism of the needles -press fit needle -needle length -Orientation of the tips
Description of the materials and components Filters	Filter A Nesat  Filter B High Volume 	Material: Filter has been mounted on the mouthpiece Colour: White / White RAL: 9003 Application: Low resistant Must be bioequivalent to originator devices (BreezeHaler or Cyclohaler). Use: High resistant Must be bioequivalent to Handyhaler

13 RESPIRATOY DEVICE RESISTANT DATA

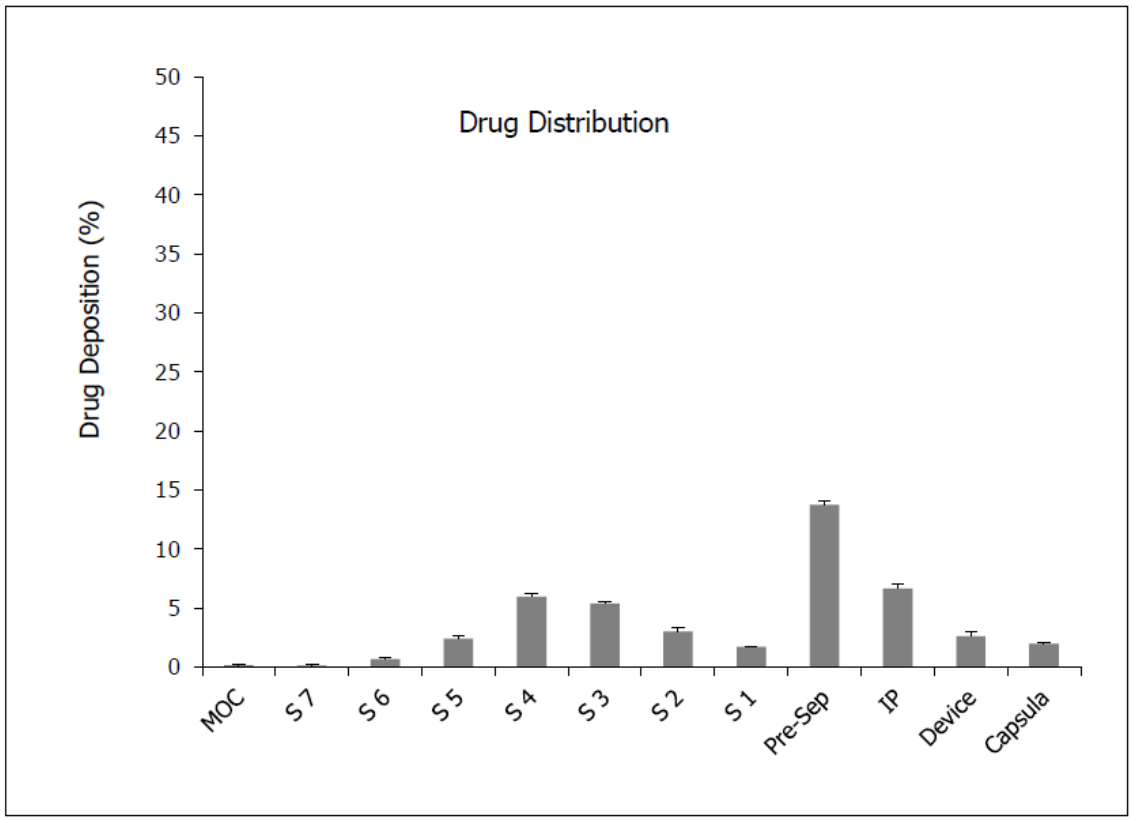
Operative Condition:

- Air flow 47 l/min
- Breathe-in time 5.1 sec
- Nr° of capsule per test 4 capsule
- drug content of each capsule 12µg

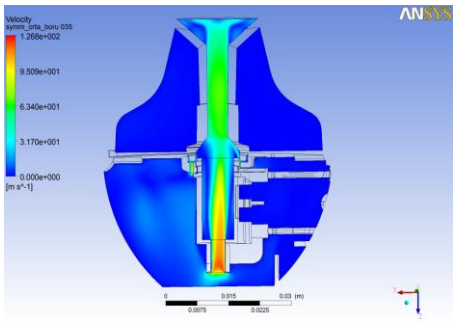
Aerodynamic parameters of the nesat device

Metered dose (µg)	Emitted (µg)	MMAD (µm)	FPD (µg)	FPF (%)	Extra_FPD (µg)	Extra-FPF (µg)
11.18±0.78	9.94± 0.20	3.37± 0.20	3.45± 0.20	34.71± 1.30	2.14± 0.08	21.58± 0.83

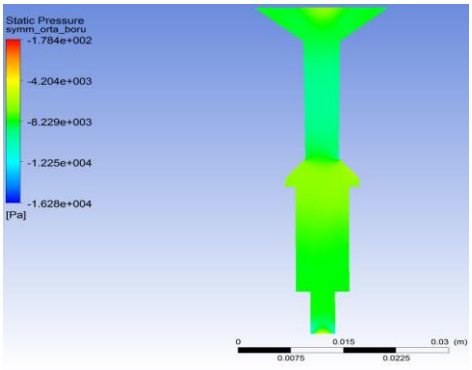
Drug Distribution:

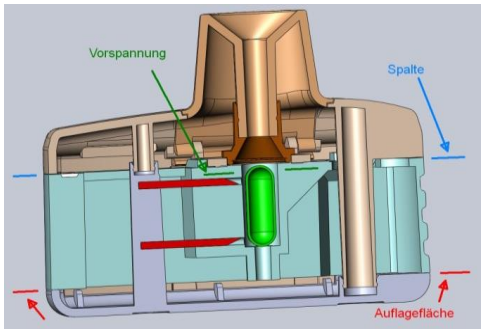


Air Path calculation of Nesat device:



- Air path dimension equal with the Handi haler BI device.
- Air path can be modified in pressure drop by filter change.
- Capsule size 3, HPMC
- Target formulation: 5-15 mg
- 4kPa =39 L/min, at 3,1sec = 2L total
- PIF 30l/min
- delivered doses range: ±20% of the nominal dose
- delivered dose range: ±25% of the label claim
- Fine particle fraction (FPF, defined as fraction of particles less than 5 µm in diameter):

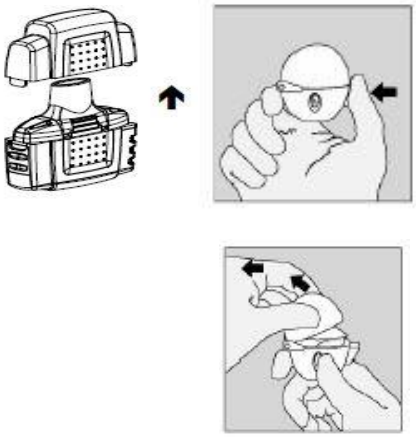




14 FUNCTIONAL DESCRIPTION PIERCING / PERFORATION:

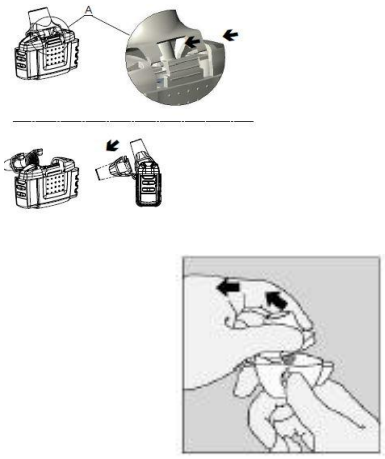
Handling description of the device "Bioequivalent to Handihaler"

1



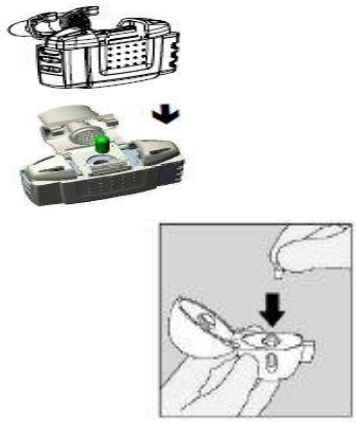
Open the dust cap by forcing upwards. Pull up the dust cap to expose the mouthpiece

2



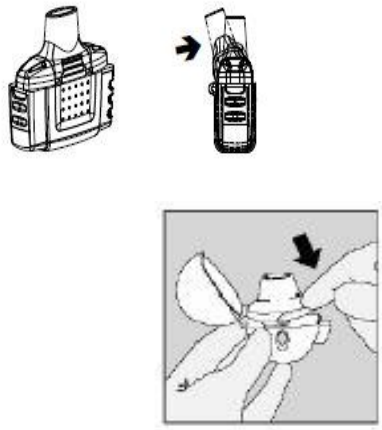
Open the mouthpiece by pulling the mouthpiece rigid upwards

3



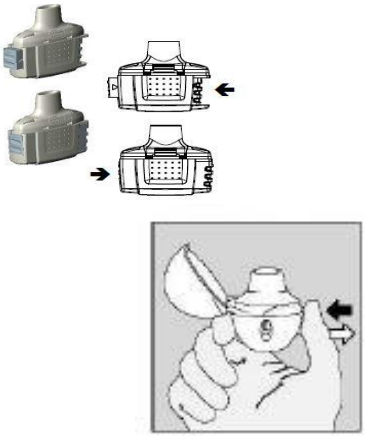
Insert the capsule in the center chamber of the handihaler device

4



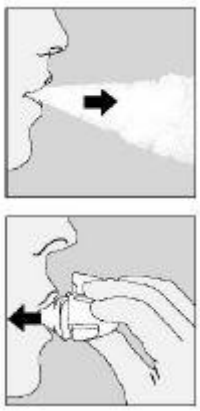
Close the mouthpiece firmly until you hear the click

5



Push the slider at the one end until it pierced the capsule and push it back

6

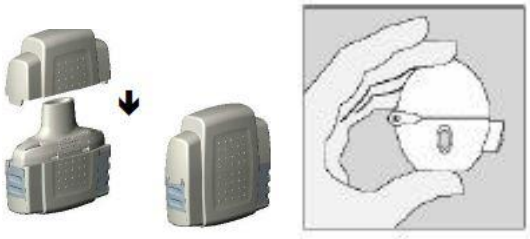


Important breath out completely. Breathe slowly but at a rate sufficient to hear or feel the capsule vibrate. Hold breath for some time leave it slowly after sometime.

7

After you finish taking the dose, open the mouthpiece and throw out the capsule

8



Close the mouthpiece and dust cap for storage of your handihaler device

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/EEC from (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 Nesat 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 Nesat. Layout Drawing of the device with the dimension Plastic Parts of the device with Material Certificates Metal parts with Material specification CE Confirmation Declaration

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