

SECTION 1: Identification of the substance / mixture and company identification**1.1 Product identifier:** DR. MAYER KERASEPT**1.2 Relevant identified uses of the substance or mixture and uses advised against:**

Identified use: Powder for medical tool disinfection. Professional use only.

The use discouraged: not specified

1.3 Details of the supplier of the safety data sheet**Manufacturer:** MEDISEPT Sp. z o.o.
Konopnica 159C
21-030 Motycz, Poland
tel. 048 81 503 23 77
www.medisept.pl**Distributor:** DENTSTORE SRL
Tepes Voda 89, Sector 2, Bucuresti, Romania
Tel. 021 308 57 51
www.dentstore.roE-mail of the person responsible for the safety data sheet: : g.gromadzki@medisept.pl**1.4 Emergency telephone number:** +48 81 535 22 22 at time: 8.00 a.m. – 4.00 p.m.
112 (general emergency number)**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****In accordance with Regulation 1272/2008:**

Acute Tox. 4; H302

Eye Dam. 1; H318

The threat to human health

Harmful if swallowed. Causes serious eyes damage

Environmental hazards

No.

Physical/chemical hazards

No.

2.2 Label elements:**Pictograms:****Signal word:** Danger**Hazard statements****H302** – Harmful if swallowed**H318** - Causes serious eye damage**Phrases indicating conditions of safe use:**

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P270 - Do not eat, drink or smoke when using this product.

P301+312: IF SWALLOWED: Call a POISON CENTER/doctor.

P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 - Immediately call a POISON CENTER/doctor/

Contains:

Sodium carbonate, compound with hydrogen peroxide (2:3) (cas: 15630-89-4)

In accordance with Regulation 648/2004

>30% oxygen-based bleaching agents

<5% non-ionic surfactants

<5% phosphonates,

Enzymes

The surfactants comply with the biodegradability in accordance with Reg. 648/2004

List of components available on website: <http://www.medisepi.pl/>

2.3 Other hazards:

No information as to the compliance with PBT or vPvB criteria, as per Annex XIII to the REACH regulation.

SECTION 3: Composition/information on ingredients
3.1 Substance: Not applicable

3.2 Mixture: Hazardous components

Product identifier	Content %	Classification CLP	
		Hazard class and category codes	Codes hazard statements
Disodium carbonate, compound with hydrogen peroxide (2:3) CAS: 15630-89-4 CE: 239-707-6 REACH no.: 01-2119457268-30	30 – 50	Ox. Sol. 3 Acute Tox. 4 Eye Dam. 1	H272 H302 H318
Adypic Acid CAS: 124-04-9 WE: 204-673-3 Index no: 607-144-00-9 REACH no.: 01-2119457561-38-XXXX	<25	Eye Irrit. 2	H319
Alcohols, secondary C11-15, ethoxylated CAS: 68131-40-8 CE: 614-295-4 Index no : - REACH no.: 01-2119560577-29-0000	<5	Eye Dam. 1 Skin irrit. 2	H318 H315
(1-hydroxyethylidene)bisphosphonic acid, sodium salt CAS: 29329-71-3 CE: 249-559-4 Index no : - REACH no.: 01-2119510382-52-XXXX	<3	Met. Corr. 1 Acute Tox. 4 Eye Irrit. 2	H290 H302 H319

Full text of H phrases In Section 16

SECTION 4: First Aid Measures**4.1 Description of first aid measures****Skin contact:**

Remove contaminated clothing, wash affected skin with soap and water, rinse thoroughly with water. In the event of an irritation, erythema, contact your doctor.

Eye contact:

Rinse eyes for several minutes (approx. 15) with plenty of water, holding the eyelids apart. Avoid strong stream, due to the risk of cornea damage, consult a doctor.

Inhalation:

In case of dizziness or nausea, remove casualty to fresh air, in the absence of rapid improvement, seek medical advice.

Ingestion:

Do not induce vomiting, rinse your mouth. Immediately contact your doctor.

4.2 Most important symptoms and effects, both acute and delayed :

Respiratory system: Inhalation of concentrated vapours may cause irritation of the mucous membranes of the nose, throat and downstream sections of the respiratory system.

Digestive tract: Ingestion causes irritation of the mucous membranes of the gastrointestinal tract, abdominal pain, stomach cramps, nausea, vomiting, diarrhea, malaise, headaches and dizziness - symptoms of food poisoning.

Eye contact: Causes serious eye damage.

Skin contact: Cause skin irritation.

4.3 Indication of any immediate medical attention and special treatment needed:

Decision on the rescue procedure is taken by a doctor following thorough examination of victim's condition

SECTION 5: Fire fighting measures**5.1 Extinguishing media:**

Suitable extinguishing media: : Alcohol-resistant foam or dry chemicals (A, B, C), carbon dioxide (fire-extinguisher), sand or soil, water spray. Use fire extinguishing methods suitable to the environment.

Unsuitable extinguishing media: A strong stream of water.

5.2 Special hazards arising from the substance or mixture:

During a fire releases oxygen, may keep fire going on.

5.3 Advice for fire-fighters:

Cool containers with spray water. If possible remove from the danger zone. As in any fire, wear self-contained breathing apparatus and full protective gear. Prevent fire-fighting water from entering surface water, ground water and sanitation.

SECTION 6: Accidental release measures**6. Personal precautions, protective equipment and emergency procedures:**

For non-emergency personnel: Inform the appropriate service. Remove from the hazardous area people not involved in liquidation of failure.

For emergency responders: Ensure adequate ventilation, use personal protective equipment. Do not breathe vapors.

6.2 Environmental precautions:

Prevent from spreading or entering into drains and reservoirs, to inform local authorities if you fail to provide protection.

6.3 Methods and material for containment and cleaning up :

Gather by mechanical means (shovels etc). Contaminated material placed in properly labeled containers. The contaminated material placed in properly labeled containers for disposal in accordance with applicable regulations.

6.4 Reference to other sections:

Waste product handling – see section 13 of the Safety Data Sheet.

Individual protection measures – see section 8 of the Safety Data Sheet.

SECTION 7: Handling and Storage

7.1 Precautions for safe handling:

Use in well-ventilated area. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Avoid spilling or splashing. Avoid breathing vapors of solutions. Avoid sources of ignition, heat, hot surfaces and open flames. Work in accordance with safety and hygiene: Do not eat, drink and smoke in the workplace, wash hands after use, remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities:

Store in a cool, dry, well-ventilated properly labeled original container tightly closed. Avoid direct sunlight and heat sources, hot surfaces and open flames. Store at temperature 5-25 C.

7.3 Specific end use(s):

Powder for medical tool disinfection. Professional use only.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters:

Exposure standards for occupational hazards in accordance with the Regulation of the Minister of Labour and Social Policy of 12 June 2018 on maximum permissible concentration and intensity of harmful factors in the work environment (polish Journal of Laws, item. 1286).

Exposure limits (ACGIH):

Name / type of substance	TWA	STEL
	ppm	
Adypic acid (respiratory)	5	10
Hydrogen peroxide	0,4	0,8

DNEL Values for Adypic acid (respiratory)

Worker DNEL, acute Systemic effects inhalation 264 mg/m³

Worker DNEL, acute Systemic effects dermal 38 mg/kg Body weight

Worker DNEL, acute Local effects inhalation 5 mg/m³

Worker DNEL, longterm Systemic effects inhalation 264 mg/m³

Worker DNEL, longterm Systemic effects dermal 38 mg/kg Body weight

Worker DNEL, longterm Local effects inhalation 5 mg/m³

Consumer DNEL, acute Systemic effects inhalation 65 mg/m³

Consumer DNEL, acute Systemic effects dermal 19 mg/kg Body weight

Consumer DNEL, acute Systemic effects oral 19 mg/kg Body weight

Consumer DNEL, longterm Systemic effects inhalation 65 mg/m³

Consumer DNEL, longterm Systemic effects dermal 19 mg/kg Body weight

Consumer DNEL, longterm Systemic effects oral 19 mg/kg Body weight

PNEC Values for Adypic acid

PNEC Fresh water sediment 0.484 mg/kg

PNEC Marine water 0.0126 mg/l

PNEC Marine sediment 0.0484 mg/kg

PNEC Aquatic intermittent release 0.46 mg/l

PNEC Sewage treatment plant 59.1 mg/l

PNEC Soil 0.0228 mg/kg

DNEL Disodium carbonate, compound with hydrogen peroxide (2:3)

Worker DNEL, acute Local effects dermal 12,8 mg/ cm²

Worker DNEL, longterm Local effects dermal 12,8 mg/ cm²

Worker DNEL, longterm Local effects inhalation 5 mg/m³

Consumer DNEL, Acute local effects dermal 6,4 mg/ cm²

Consumer DNEL, Long-term local effects dermal 6,4 mg/cm²

PNEC Values for Disodium carbonate, compound with hydrogen peroxide (2:3)

PNEC Fresh water 0,035 mg/l

PNEC Marine water 0,035 mg/l

PNEC Aquatic intermittent release 0,035 mg/l

DNEL Values for hydrogen peroxideWorker DNEL, acute Local effects inhalation 3 mg/m³Worker DNEL, longterm Local effects inhalation 1,4 mg/m³Consumer DNEL, acute Local effects inhalation 1,93 mg/m³Consumer DNEL, longterm Local effects inhalation 0,21 mg/m³**PNEC Values for hydrogen peroxide**

PNEC Fresh water 0,0126 mg/l

PNEC Marine water 0,0126 mg/l

PNEC Aquatic intermittent release 0,0138 mg/l

PNEC Sewage treatment plant 4,66 mg/l

PNEC Fresh water sediment 0,47 mg/kg

PNEC Marine sediment 0,47 mg/kg

PNEC Soil 0,0023 mg/kg

(1-hydroxyethylidene)bisphosphonic acid, sodium salt**DNEL Values**

The DNELs are those of the active acid.

DNEL (oral, long-term, workers): 13 mg/kg/day

DNEL (oral, long-term, consumers): 6,5 mg/kg/day

PNEC Values

The PNECs are those of the active acid.

PNEC (aqua-freshwater): 0,136 mg/l

PNEC (aqua-marine water): 0,0136 mg/l

PNEC (marine-CHARM): 0,068 mg/l

PNEC (sediment (freshwater)): 59 mg/kg sediment wwt

PNEC (sediment (marine water)): 5,9 mg/kg sediment wwt

PNEC (soil): 96 mg/kg wwt

PNEC (sewage treatment plant): 20 mg/l

PNEC (oral): 12 mg/kg food

8.2 Exposure controls:**Technical solutions:** recommended well-ventilated areas.**Individual protection measures, such as personal protective equipment (if working with concentrated product):**

Safety Glasses



Gloves

Eye and face protection:

Wear safety glasses or full face mask (according to EN 166).

Skin protection:**Hand protection:**

Wear protective gloves resistant to chemicals made of nitrile rubber, natural rubber or PVC, in accordance with EN-PN 374: 2005.

Gloves material:

Choice of suitable gloves do not depend only on material but brand and quality. Material resistance can be defined after testing. Exact destruction time must be declared by manufacturer.

Other:

Wear appropriate protective work wear (according to EN 344) - wash regularly.

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Respiratory protection:

Do not breath vaporous

Thermal hazards:

Not applicable.

Environmental exposure controls:

Do not allow to spread in the environment and enter drains and watercourses.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties:**

Appearance	White powder
Colour	White
Odour	acetic
Odour threshold	Not specified
pH	8+/- 0,75 (1% i n water)
Melting point/range	Not specified
Boiling point/range	Not specified
Flash point	Not specified
Ignition	Not specified
Evaporation rate	Not specified
Vapour pressure at 20 ° C	Not specified
Relative vapor density	Not specified
Density	0,650g/cm ³ +/- 0,05
Solubility in solvents	soluble in water (about 2%)
Coefficient of n-octanol / water	Not specified

9.2 Other information: No additional test results.**SECTION 10: Stability and reactivity****10.1 Reactivity :**

Has a fire-promoting effect due to release of oxygen.

10.2 Chemical stability:

heat-sensitive

10.3 Possibility of hazardous reactions:

No

10.4 Conditions to avoid :

Avoid high temperature, direct sunlight, hot surfaces and open fire.

10.5 Incompatible materials :

Acids, heavy metal salts, redactors, organic substances.

10.6 Hazardous decomposition products :

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At high temperatures, they release toxic products of decomposition – oxygen, carbon oxides and nitrogen oxides

SECTION 11: Toxicological information**11.1 Information on toxicological effects:**a) Acute toxicity: **Harmful if swallowed****Adypic Acid**

LD50 (oral, rat): 5560mg/kg (OECD 401)

LC50 (rat, skin): 7.7 mg/l; 4 h ; dust/mist (OECD 403)

Acute dermal toxicity

LD50 Rabbit: > 7,940 mg/kg (40% solution) (External MSDS)

Skin irritation

Rabbit Result: No skin irritation OECD Test Guideline 404

Eye irritation

Rabbit Result: Severe irritations OECD Test Guideline 405

Causes serious eye irritation.

Sensitisation

Maximisation Test Guinea pig

Result: negative (External MSDS)

Germ cell mutagenicity

Genotoxicity in vitro

Ames test Escherichia coli/Salmonella typhimurium

Result: negative Method: OECD Test Guideline 471**In vitro mammalian cell gene mutation test**

Chinese hamster lung cells

Result: negative

Method: OECD Test Guideline 476

b) irritation effect: causes skin irrit.

c) corrosive effect: causes serious eye damage

d) allergic effect: not recognized

e) repeated dose toxicity: not recognized

f) carcinogenicity: not recognized

g) mutagenicity: not recognized

h) reproductive toxicity: not recognized

Disodium carbonate, compound with hydrogen peroxide (2:3)

LD50 oral, rat: 1034mg/kg

LD50 skin, rabbit: >2000mg/kg

Adypic acid

LD50 oral, rat: 5560mg/kg

LD50 skin, rabbit >7940mg/kg

LC50 inhalation, rat: >7,7mg/l, 4h

Alcohols, secondary C11-15, ethoxylated

LD50 oral, rat: >3000mg/kg

LD50 skin, rabbit: >2000mg/kg

(1-hydroxyethylidene)bisphosphonic acid, sodium salt

LD50 oral, rat: 300 - 2000mg/kg

Information on likely routes of exposure:

The respiratory system. Inhalation of powder suspension may cause irritation of the mucous membranes of the nose, throat and downstream sections of the respiratory system, cough, shortness of breath, trouble breathing. May cause drowsiness or dizziness

The digestive tract: May cause irritation of the mucous membranes of the gastrointestinal tract, abdominal pain, stomach cramps, nausea, vomiting, diarrhea, malaise, headache and dizziness – symptoms of food poisoning.

Eye contact: causes serious eye damage

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Contact with skin: may cause skin irritation.

Delayed, immediate and chronic effects from short-and long-term exposure:

No data.

Interaction effect:

No data.

SECTION 12: Ecological information

Detailed studies of the environmental effects were not carried out. Harmful to aquatic life with long-lasting effects.

12.1 Toxicity:**Adypic acid**

Toxicity to fish

LC50 Pimephales promelas (fathead minnow): 97 mg/l; 96 h (ECOTOX Database)

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia magna (Water flea): 46 mg/l; 48 h OECD Test Guideline 202

Toxicity to algae

static test ErC50 Pseudokirchneriella subcapitata (green algae): 59 mg/l; 72 h OECD Test Guideline 201

Toxicity to bacteria

EC50 Pseudomonas putida: 92 mg/l; 17 h DIN 38412

static test EC50 activated sludge: 7,911 mg/l; 3 h

OECD Test Guideline 209

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC Daphnia magna (Water flea): 6.3 mg/l; 21 d

OECD Test Guideline 211

hydrogen peroxide

Toxicity to fish

LC50 Pimephales promelas (fathead minnow): 16,4 mg/l; 96 h (IUCLID)

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia magna (Water flea): 2,3 mg/l; 48 h (ECOTOX Database)

NOEC Daphnia magna (Water flea): 0,63 mg/l; 21 d (External MSDS)

Toxicity to algae

IC50 Pseudokirchneriella subcapitata (green algae): 5,7 mg/l; 72 h (ECOTOX Database)

Growth rate NOEC Skeletonema costatum: 0,63 mg/l; 72 h (External MSDS)

Toxicity to bacteria

static test EC50 activated sludge: 466 mg/l; 30 min OECD Test Guideline 209

static test EC50 activated sludge: > 1.000 mg/l; 3 h OECD Test Guideline 209

(1-hydroxyethylidene)bisphosphonic acid, sodium salt

Aquatic toxicity:

LC 50 (Salmo gairdneri) > 100 mg/L 96h

EC 50 (Daphnia magna) > 170 mg/L 96h

12.2 Persistence and degradability:

Surfactants are included in the product are consistent with the regulations concerning biodegradation.

Adypic Acid

Biodegradability

100 %; 28 d OECD Test Guideline 301B

Readily biodegradable

Biochemical Oxygen Demand (BOD)

598 mg/g (5 d)(IUCLID)

Theoretical oxygen demand (ThOD)

1,423 mg/g (IUCLID)

Ratio BOD/ThBOD BOD5 36 % (Lit.)

12.3 Bioaccumulative potential:**Adypic acid**

Partition coefficient: n-octanol/water

log Pow: 0.081 (25 °C) OECD Test Guideline 107

12.4 Mobility in soil:

Mobile in the soil, dissolved in water and spread in an aquatic environment.

Adypic Acid

No adsorption on soil particles.

Disodium carbonate, compound with hydrogen peroxide (2:3)

Soil/sludge: negligible adsorption

12.5 Results of PBT and vPvB assessment:

No data.

12.6 Other adverse Effects:**Adypic acid**

Biological effects:

Harmful effect due to pH shift.

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations**13.1 Waste treatment methods:**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorized for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed with municipal waste. Empty containers may be used at waste incinerators or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

SECTION 14: Transport information

	ADR/RID	IMDG	IATA
Transport route	Not applicable, the product is not classified as hazardous during transport		
14.1 – UN number	Not applicable, the product is not classified as hazardous during transport		
14.2 – Proper transport name UN	Not applicable, the product is not classified as hazardous during transport		
14.3 – Transport hazard class(es):	Not applicable, the product is not classified as hazardous during transport		
14.4 – Packing group	Not applicable, the product is not classified as hazardous during transport		
14.5 – Environmental hazards	Not applicable, the product is not classified as hazardous during transport		
14.6 – Special precautions for users	Not applicable, the product is not classified as hazardous during transport		
14.7 – Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable, the product is not classified as hazardous during transport		

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

1. The ordinance 1907/2006 (EC) of the European Parliament and Council, dated in 18 December 2006, on registration, evaluation, permissions and restrictions for chemicals (REACH), along with later modifications.
2. Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).
3. Law of 25 February 2011 on chemical substances and their mixtures (Journal of Laws No. 63, item. 322, along with later modifications)

4. European Parliament and Council Regulation of 16 December 2008 no. 1272/2008 (CLP) along with later modifications.
5. Ministry of Health Regulation of 20 April 2012 on dangerous substances and mixtures container labelling and certain mixtures (Journal of Laws 2012 No. 0 item. 445, along with later modifications)
6. Ministry of Health Regulation of 10 August 2012 on classification types and criteria of chemical substances and their mixtures (Journal of Laws 2012 item. 1018, along with later modifications)
7. Law of 9 December 2012 on waste list (Journal of Laws 2013 No. 0, item.21).
8. The Law of 13 June 2013 on packaging and packaging waste (Journal of Laws 2013, item. 888).
9. Regulation of the the Minister of Environment of 9 december 2014 on waste catalog (Journal of Laws No. 1923)
10. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended.
11. The Law of 19 August 2011. on the transport of dangerous goods (Journal of Laws No. 227, item. 1367)
12. Government Statement of 23 March 2015. On the entry into force of amendments to Annexes A and B of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), done at Geneva on 30 September 1957. (Journal of Laws 2015, item. 882).
13. Regulation of the Minister of Labour and Social Policy of 12 June 2018 on maximum permissible concentration and intensity of harmful factors in the work environment (Journal item. 1286).
14. Regulation of the Minister of the Environment of 9 December 2003 on substances posing a particular threat to the environment (Journal of Laws No. 217, item.2141).

15.2 Chemical safety assessment: No chemical safety assessment for the mixture.

SECTION 16: Other information

Phrases H:

H272 May intensify fire; oxidizer

H290 May be corrosive to metals

H302 Harmful if swallowed

H315 Causes skin irritation

H318 Causes serious eye damage

H319 Causes serious eye irritation

Description of used abbreviations, acronyms and symbols:

Ox. Sol. 3 – solid oxidizing cat.3

Met. Corr. 1 – metal corrosive, cat.1

Acute Tox. 4 – acute toxicity cat. 4

Skin Corr.1A – corrosive effect on skin cat.1A

Skin Corr.1B – corrosive effect on skin cat.1B

Eye Dam, 1 – causes serious eye damage, cat.1

Eye Irrit. 2– causes eye irritation, cat.2

Skin Irrit. 2– causes skin irritation, cat.2

LC50 – (ang. **lethal concentration**) **medium** mortality dose of 50% in population of test organisms in long exposure

LC50 – (ang. **lethal concentration**) **medium** mortality dose of 50% in population of test organisms in 1 time exposure

NOAEL (**no observed adverse effects level**) - the highest experimental point that is without adverse effect

TWA – Time weighted Average exposure limit

STEL – Acceptable Ceiling

DNEL - (**Derived no-effect level**) is the level of exposure to a substance above which humans should not be exposed.

PNEC (**Predicted No Effect Concentration**) is the concentration of a chemical which marks the limit at which below no adverse effects of exposure in an ecosystem are measured.

IATA International Air Transport Association

ADR a treaty governing transport of hazardous materials

IMDG International Maritime Dangerous Goods Code is accepted as an international guideline to the safe transportation or shipment of dangerous goods or hazardous materials by water on vessel

Training:

Before working with product carry out OSH training for stuff related to the presence of chemical factor in the work environment. Carry out, register and inform employees about the evaluation of professional risk of working in presence of chemical factors

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- Changes: section 1, 2, 8, 15

SOURCE MATERIALS

Appendix I of EC Regulation 2015/830 of 28 May 2015

Regulations detailed in Section 15 of this document

MSDS – DR. MAYER KERASEPT v 1.0 EN

The information provided in this Safety Data Sheet concern only in the title mentioned product. The information given is designed as a guidance for safe handling, use, storage, transportation, disposal and it is not to be considered as legal warranty. In any case, you must comply with the laws and the possible rights of third parties. Sheet is not workplace risk assessment. Product cannot be used in other purpose then mentioned in section 1 without previous consultation with **MEDISEPT Sp z o.o.**